Exhibit

A

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

FTC Issues Final Rule Establishing Process for Horseracing Integrity and Safety Authority's Submission of Proposed Rules

September 28, 2021

Changes to FTC Rules of Practice establish processes under 2020 horseracing safety law

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The Federal Trade Commission has made updates to its Rules of Practice, establishing a formal process by which the Horseracing Integrity and Safety Authority can submit its draft rules and procedures to the FTC for review and an approval decision.

Under the Horseracing Integrity and Safety Act of 2020, the FTC is required to review and decide whether to approve or disapprove rules proposed by the Authority in a number of areas, such as anti-doping and racetrack safety. The new procedural rules establish requirements applicable to the Authority for its submission of proposed rules to the Commission for review.

The new procedural rules identify what the Authority must submit to the Commission for the Commission to evaluate and decide whether to approve or disapprove the Authority's proposed rules. The Authority's proposed rules will be published in the Federal Register for public comment.

Consistent with the Act, the new procedural rules require the Commission to approve or disapprove of any proposed rules or rule modifications submitted by the Authority within 60 days of their being published in the Federal Register.

The Commission vote to approve the changes to the FTC Rules of Practice was 5–0. The changes will be published in the Federal Register shortly.

The Federal Trade Commission works to promote competition, and protect and educate consumers. You can learn more about consumer topics and file a consumer complaint online or by calling 1-877-FTC-HELP (382-4357). For the latest news and resources, follow the FTC on social media, subscribe to press releases and read our blogs.

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ftc.gov

Exhibit

B

Control(s)	Country chart (see Supp. No. 1 to part 738)
MT applies to ''technology'' for items controlled by 2B004, 2B009, 2B104, 2B105, 2B109, 2B116, 2B117, 2B119 to 2B122, 2D001, or 2D101 for MT reasons.	MT Column 1.
NP applies to ''technology'' for items controlled by 2A225, 2A226, 2B001, 2B004, 2B006, 2B007, 2B009, 2B104, 2B109, 2B116, 2B201, 2B204, 2B206, 2B207, 2B209, 2B225 to 2B233, 2D001, 2D002, 2D101, 2D201, or 2D202 for NP reasons.	NP Column 1.
NP applies to ''technology'' for items controlled by 2A290, 2A291, or 2D290 for NP reasons.	NP Column 2.
CB applies to ''technology'' for equipment controlled by 2B350 to 2B352, valves controlled by 2A226 having the characteristics of those controlled by 2B350.g, and software controlled by 2D351 or 2D352.	CB Column 2.
AT applies to entire entry.	AT Column 1.

Reporting Requirements

See § 743.1 of the EAR for reporting requirements for exports under License Exceptions, and Validated End-User authorizations.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except N/A for MT

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit ''technology'' according to the General Technology Note for the ''development'' of ''software'' specified in the License Exception STA paragraph in the License Exception section of ECCN 2D001 or for the ''development'' of equipment as follows: ECCN 2B001 entire entry; or ''Numerically controlled'' or manual machine tools as specified in 2B003 to any of the destinations listed in Country Group A:6 (See Supplement No. 1 to part 740 of the EAR).

List of Items Controlled

Related Controls: See also 2E101, 2E201, and 2E301

Related Definitions: N/A

Items:

The list of items controlled is contained in the ECCN heading.

Note 1 to 2E001: ECCN 2E001 includes ''technology'' for the integration of probe systems into coordinate measurement machines specified by 2B006.a.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2021–21493 Filed 10–4–21; 8:45 am]

BILLING CODE 3510–33–P

FEDERAL TRADE COMMISSION

16 CFR Part 1

Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') is issuing rules pursuant to the Horseracing Integrity and Safety Act (''Act'') to provide procedures for the Horseracing Integrity and Safety Authority (''Authority'') to submit its proposed rules and proposed rule modifications to the Commission for review.

DATES: These rule revisions are effective on October 5, 2021.

FOR FURTHER INFORMATION CONTACT: Austin King (202–326–3166), Associate General Counsel for Rulemaking, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: The Horseracing Integrity & Safety Act,[1] enacted on December 27, 2020, directs the Federal Trade Commission to oversee the activities of a private, self-regulatory organization called the Horseracing Integrity and Safety Authority.

Section 4(a) of the Act, 15 U.S.C. 3053(a), requires the Authority to submit to the Commission, in accordance with such rules as the Commission may prescribe under Section 553 of Title 5, United States Code, any proposed rule, or proposed modification to a rule, of the Authority relating to: (1) The bylaws of the Authority; (2) a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods; (3) laboratory standards for accreditation and protocols; (4) standards for racing surface quality maintenance; (5) racetrack safety standards and protocols; (6) a program for injury and fatality data analysis; (7) a program of research and education on safety, performance, and anti-doping and medication control; (8) a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons; (9) a schedule of civil sanctions for violations; (10) a process or procedures for disciplinary hearings; and (11) a formula or methodology for determining the assessments described in 15 U.S.C. 3052(f).

Accordingly, the Commission is adding a new subpart S to part 1 of its Rules of Practice, to provide procedures for the Authority to file its proposed rules and proposed modifications to existing rules with the Commission for review.

I. Section 1.140—Definitions

Section 1.140 defines relevant terms used in the proposed regulations. Each definition is based on a corresponding definition contained in Section 2 of the Act, 15 U.S.C. 3051, except as otherwise noted below.

The definition of ''HISA Guidance'' derives from Section 5(g)(1) of the Act, 15 U.S.C. 3054(g)(1), which states the Authority may issue guidance that ''sets forth an interpretation of an existing rule, standard, or procedure of the Authority'' or a ''policy or practice with respect to the administration or enforcement of such an existing rule, standard, or procedure'' and ''relates solely to the administration of the Authority; or any other matter, as specified by the Commission, by rule, consistent with the public interest and the purposes of this subsection [15 U.S.C. 3054(g)(1)].'' The Commission is adopting this definition and adding that HISA Guidance does not have the force of law, to distinguish HISA Guidance from a proposed modification to a rule.

The Act does not contain definitions for ''proposed rule'' or ''proposed modification.'' However, because these terms are used frequently throughout the regulations, the Commission is defining them for clarity. ''Proposed rule'' is defined as any rule proposed by the Authority pursuant to the Act. ''Proposed rule modification'' or ''modification'' is defined as any proposed modification to a rule, proposed rule change, or any interpretation or statement of policy or practice relating to an existing rule of the Authority that is not HISA Guidance and would have the force of law if

[1] 15 U.S.C. 3051 through 3060.

approved as a final rule. A proposed modification is distinguished from HISA Guidance in that a modification would have the force of law if approved and must therefore be approved by the Commission pursuant to Section 4(b)(2) of the Act, 15 U.S.C. 3053(b)(2). HISA Guidance need not be approved by the Commission but takes effect upon submission to the Commission pursuant to Section 5(g)(3) of the Act, 15 U.S.C. 3054(g)(3).

II. Section 1.141—Required Submissions

The Act requires the Authority to submit proposed rules or proposed rule modifications on certain subjects to the Commission for approval. These subjects are set forth in Section 4(a) of the Act, 15 U.S.C. 3053(a), which states the Authority must submit to the Commission, in accordance with such rules as the Commission may prescribe under Section 553 of Title 5, any proposed rule, or proposed modification to a rule, of the Authority relating to: (1) The bylaws of the Authority; (2) a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods; (3) laboratory standards for accreditation and protocols; (4) standards for racing surface quality maintenance; (5) racetrack safety standards and protocols; (6) a program for injury and fatality data analysis; (7) a program of research and education on safety, performance, and anti-doping and medication control; (8) a description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons; (9) a schedule of civil sanctions for violations; (10) a process or procedures for disciplinary hearings; and (11) a formula or methodology for determining assessments described in 15 U.S.C. 3052(f). The Commission is adopting this language in its regulations.

The Commission is also adding a provision that the Authority must submit ''any other proposed rule or modification the Act requires the Authority to submit to the Commission for approval.'' For instance, the Act requires the Authority to submit rules regarding modifications to baseline anti-doping standards (15 U.S.C. 3055(g)(3)(b)) and modifications to racetrack safety rules (15 U.S.C. 3056(c)(2)(B)(ii)). Section 5(c)(2) of the Act, 15 U.S.C. 3054(c)(2), requires the Authority to submit to the Commission for approval any rules and procedures under Section 5(c)(1)(A) of the Act, 15 U.S.C. 3054(c)(1)(A), authorizing access to offices, racetrack facilities, other places of business, books, records, and personal property of covered persons used in the care, treatment, training, and racing of covered horses; authorizing the issuance and enforcement of subpoenas and subpoenas duces tecum; and authorizing other investigatory powers of the nature and scope exercised by State racing commissions before the program effective date. Such proposed rules and modifications must also be submitted to the Commission for approval.

III. Section 1.142—Submission of Proposed Rule or Modification

The Act requires the Commission to evaluate the Authority's proposed rules and modifications to determine whether they are consistent with the Act and the applicable rules approved by the Commission. *See* 15 U.S.C. 3053(c)(2). To avoid delays in the rule review process, the Commission is requiring the Authority to submit the information necessary for it to evaluate the proposed rule or modification promptly and efficiently. Section 1.142 is designed to elicit the information the Commission needs to determine whether the proposed rule or modification is consistent with the Act and the rules and regulations issued thereunder.

A. Contents of Submission

For a submission to qualify as a proposed rule or proposed modification to a rule under Section 4(a) of the Act, 15 U.S.C. 3053(a), the Authority must submit a complete draft of the **Federal Register** document for its proposed or modified rule, which includes the text of the rule and a statement of the purpose of, and statutory basis for, the proposed rule or modification. The Commission's intention is to require the Authority to provide an explanation of its rules that will allow both the Commission and the public to understand the nature and purpose of its proposed rules or modifications—the reasons for adopting the proposed rule or modification; any problems the proposed rule or modification is intended to address and how the proposed rule or modification will resolve those problems; and how the proposed rule or modification will affect covered persons, covered horses, and covered horseraces.

The Commission is also requiring the Authority to explain the statutory basis for its proposed rules or modifications. To evaluate a proposed rule or modification, the Commission must be able to understand why the Authority believes its proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. Evaluation of a proposed rule or modification will also be aided by the Authority's description of any reasonable alternatives it considered and the reasons it selected the proposed rule or modification over the alternatives.

The Act does not give the Authority broad discretion in developing rules. It sets forth guardrails, in the form of baseline standards for anti-doping and medication control (15 U.S.C. 3055(g)(2)(A)), racetrack safety standards which the Authority must consider (15 U.S.C. 3056(a)(2)), guidelines for determining funding and calculating costs (15 U.S.C. 3052(f)(1)(C)(ii)), a specific formula for the assessment and collection of fees (15 U.S.C. 3052(f)(3)(C)), who must register with the Authority and the conditions of registration (15 U.S.C. 3054(d)), guidelines for establishing rule violations (15 U.S.C. 3057(a)(2)), requisite elements of the Authority's results management and disciplinary program (15 U.S.C. 3057(c)(2)), guidelines for establishing civil sanctions (15 U.S.C. 3057(d)(2)), and more. Accordingly, the Authority must explain why its proposed rule or modification is consistent with any standards in the Act and the rules approved by the Commission. Because the requisite considerations for anti-doping and racetrack safety are the most prescriptive, this section specifically addresses those standards and factors. The less prescriptive standards and factors must also be addressed, and the Commission provides for this in a less prescriptive rule, as discussed below.

1. Anti-Doping and Medication Control Program Considerations

When proposing a rule or modification to the horseracing anti-doping and medication control program, the Authority must explain how it considered the factors in Section 6 of the Act, 15 U.S.C. 3055, including the unique characteristics of a breed of horse made subject to the Act by election of a State racing commission or breed governing organization for such horse pursuant to Section 5(*l*) of the Act, 15 U.S.C. 3054(*l*), as required by Section 6(a)(2) of the Act, 15 U.S.C. 3055(a)(2). The Authority must explain how it considered the factors in Section 6(b) of the Act, 15 U.S.C. 3055(b), namely that: (1) Covered horses should compete only when they are free from the influence of medications, other foreign substances, and methods that affect their performance; (2) covered horses that are injured or unsound should not train or participate in covered races, and the use

of medications, other foreign substances, and treatment methods that mask or deaden pain in order to allow injured or unsound horses to train or race should be prohibited; (3) rules, standards, procedures, and protocols regulating medication and treatment methods for covered horses and covered races should be uniform and uniformly administered nationally; (4) to the extent consistent with chapter 57A of title 15, consideration should be given to international anti-doping and medication control standards of the International Federation of Horseracing Authorities and the Principles of Veterinary Medical Ethics of the American Veterinary Medical Association; (5) the administration of medications and treatment methods to covered horses should be based on an examination and diagnosis that identifies an issue requiring treatment for which the medication or method represents an appropriate component of treatment; (6) the amount of therapeutic medication a covered horse receives should be the minimum necessary to address the diagnosed health concerns identified during the examination and diagnostic process; and (7) the welfare of covered horses, the integrity of the sport, and the confidence of the betting public require full disclosure to regulatory authorities regarding the administration of medications and treatments to covered horses.

In addition, Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), provides that certain baseline anti-doping and medication control rules must constitute the initial rules of the horseracing anti-doping and medication control program and, except as exempted pursuant to Section 6(e) and (f) of the Act, 15 U.S.C. 3055(e) and (f), remain in effect at all times after the program effective date. Such baseline anti-doping and medication control rules include: (1) The lists of permitted and prohibited substances (including drugs, medications, and naturally occurring substances and synthetically occurring substances) in effect for the International Federation of Horseracing Authorities, including the International Federation of Horseracing Authorities International Screening Limits for urine, dated May 2019, and the International Federation of Horseracing Authorities International Screening Limits for plasma, dated May 2019; (2) the World Anti-Doping Agency International Standard for Laboratories (version 10.0), dated November 12, 2019; (3) the Association of Racing Commissioners International out-of-competition testing standards, Model Rules of Racing (version 9.2); and (4) the Association of Racing Commissioners International penalty and multiple medication violation rules, Model Rules of Racing (version 6.2). In the case of a conflict among the rules, Section 6(g)(2)(B) of the Act, 15 U.S.C. 3055(g)(2)(B), provides that the most stringent rule shall apply. Accordingly, the Commission is requiring the Authority to state whether a proposed rule adopts the baseline standards identified in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A). If there is a conflict in any baseline standards identified in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), the Authority must identify the conflict and state whether the standard it adopted is the most stringent standard. Under Section 6(g)(3)(C) of the Act, 15 U.S.C. 3055(g)(3)(C), ''[t]he Authority shall not approve any proposed modification that renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules . . . without the approval of the anti-doping and medication control enforcement agency.'' Thus, for a proposed rule modification, the Authority must explain whether the modification renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules described in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A), and state whether the anti-doping and medication control enforcement agency has approved of the change.

2. Racetrack Safety Program Considerations

Section 7 of the Act, 15 U.S.C. 3056, requires the Authority to consider certain factors when developing the racetrack safety program. Accordingly, when proposing a rule or modification to any rule regarding its racetrack safety program, the Authority must explain how the proposed rule or modification meets the requirements in Section 7(b) of the Act, 15 U.S.C. 3056(b), which provides that the horseracing safety program must include the following: (1) A set of training and racing safety standards and protocols taking into account regional differences and the character of differing racing facilities; (2) a uniform set of training and racing safety standards and protocols consistent with the humane treatment of covered horses, which may include lists of permitted and prohibited practices or methods (such as crop use); (3) a racing surface quality maintenance system that takes into account regional differences and the character of differing racing facilities (which may include requirements for track surface design and consistency and established standard operating procedures related to track surface, monitoring, and maintenance, such as standardized seasonal assessment, daily tracking, and measurement); (4) a uniform set of track safety standards and protocols, that may include rules governing oversight and movement of covered horses and human and equine injury reporting and prevention; (5) programs for injury and fatality data analysis, that may include pre- and post-training and race inspections, use of a veterinarian's list, and concussion protocols; (6) the undertaking of investigations at racetrack and non-racetrack facilities related to safety violations; (7) procedures for investigating, charging, and adjudicating violations and for the enforcement of civil sanctions for violations; (8) a schedule of civil sanctions for violations; (9) disciplinary hearings, which may include binding arbitration, civil sanctions, and research; (10) management of violation results; (11) programs relating to safety and performance research and education; and (12) an evaluation and accreditation program that ensures racetracks in the United States meet the standards described in the elements of the Horseracing Safety Program.

The Authority must also consider the safety standards in Section 7(a)(2) of the Act, 15 U.S.C. 3056(a)(2), which provide that in the development of the horseracing safety program for covered horses, covered persons, and covered horseraces, the Authority and the Commission must take into consideration existing safety standards, including the National Thoroughbred Racing Association Safety and Integrity Alliance Code of Standards, the International Federation of Horseracing Authority's International Agreement on Breeding, Racing, and Wagering, and the British Horseracing Authority's Equine Health and Welfare program. The Commission is therefore requiring the Authority to explain how it considered and whether it adopted any of the standards in Section 7(a)(2) of the Act,15 U.S.C. 3056(a)(2). If any horseracing safety standards in Section 7(a)(2) of the Act, 15 U.S.C. 3056(a)(2), were considered but not adopted or were modified, the Authority must explain why it decided not to adopt or why it decided to modify such standard.

3. Other Considerations

The Commission is incorporating the specific anti-doping and racetrack safety standards into this section because they are the most prescriptive and extensive, but this should not be read as an

invitation to dispense with the less-prescriptive guardrails set forth in the Act. To the extent the Act requires the Authority to consider any factors or standards not specifically referenced in this section, the Authority must explain whether and how it considered those factors when proposing a rule or modification. For instance, when proposing a civil sanctions rule or modification pursuant to Section 8(d)(1) of the Act, 15 U.S.C. 3057(d)(1), the Authority must explain how the rule or modification meets the requirements of Section 8(d)(2) of the Act, 15 U.S.C. 3057(d)(2).

B. Supporting Documentation

The Commission is requiring the Authority to submit any pertinent factual information it relied on in developing its proposed rule or modification. More specifically, the Authority's submission to the Commission must include a copy of existing standards used as a reference for the development of a proposed rule or modification and any scientific data, studies, or analysis underlying the development of the proposed rule or modification. The Commission anticipates receiving, for instance, a copy of the lists of permitted and prohibited substances in effect for the International Federation of Horseracing Authorities, including the International Federation of Horseracing Authorities International Screening Limits for urine, dated May 2019, and any other rules and standards referenced in Section 6(g)(2)(A) of the Act, 15 U.S.C. 3055(g)(2)(A) when the Authority's baseline rules for anti-doping are submitted. For organizational purposes, supporting documentation must be attached as exhibits, and each exhibit must clearly identify the proposed rule or modification it supports.

C. Redline Document for Proposed Rule Modification

To enable the Commission to quickly and easily identify the substance of a proposed rule modification, the Commission is requiring the Authority to provide a redline document of the existing rule, marked with the proposed changes.

D. Timing of Submission

Section 4(c)(1) of the Act, 15 U.S.C. 3053(c)(1) provides for a 60-day timeframe between the Commission's publication of the Authority's proposed rule or modification in the **Federal Register** for public comment and the date the Commission must approve or disapprove the Authority's proposed rule or modification. To ensure it has sufficient time for review, the Commission is requiring the Authority to provide the information it needs to evaluate the Authority's proposed rule or modification at least 90 days in advance of the date the Authority proposes having its proposed rule or modification published in the **Federal Register** for public comment. This will give the Commission additional time to evaluate the Authority's proposed rule or modification. It should be noted this 90-day timeframe serves as a minimum, not a maximum, timeframe. The Secretary may shorten the timeframe if the Authority demonstrates that a shorter timeframe is necessary to meet statutory deadlines.

E. Conclusory Statements and Failure To Provide Requisite Analysis

The Authority must provide an adequate basis for the Commission's review of its rules. The Commission seeks to understand the Authority's analysis of the information it relied on to determine whether a proposed rule or modification was warranted and if so, what provisions the rule should contain. To this end, the information required under this section must be sufficiently detailed and contain sufficient analysis to support a Commission finding that a proposed rule or modification satisfies the statutory requirements. A mere assertion or conclusory statement that a proposed rule or modification is consistent with the requirements of the Act, for instance, is insufficient. If the Authority fails to describe and justify the proposed rule or modification in the manner described in this section, or fails to submit the information required by this section, the Commission may not have sufficient information to make an affirmative finding that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission.

F. Public Comments

Section 4(d)(2) of the Act, 15 U.S.C. 3053(d)(2), provides the ''Commission shall publish in the **Federal Register** any [ ] proposed rule, standard, or procedure and provide an opportunity for public comment.'' However, the Act gives the Commission only a total of 60 days after publication to approve or disapprove a proposed rule or modification once it has been published in the **Federal Register**. Given that the Commission and the Authority will need time to review comments, the Act functionally provides for a much more limited comment period of approximately 30 days or less. To ensure the public has an adequate opportunity to review and understand the Authority's rules, ask questions, and provide comments, the Commission is encouraging the Authority to make its proposed rules publicly available and solicit public comments in advance of providing any submissions to the Commission. To avoid delays in Commission approval of its rules, the Authority should not wait until its proposed rule is published in the **Federal Register** to solicit its own public comments.

In a March 21, 2021 letter [2] to the Acting Chairwoman, Rebecca Kelly Slaughter, the Act's sponsors stated ''[t]he relationship between the [Commission] and the Authority is closely modeled on the enduring and effective relationship between the Securities and Exchange Commission (SEC) and Financial Industry Regulatory Authority (FINRA), a private self-regulatory organization.'' As part of its own rulemaking process, the FINRA Board of Governors may authorize the publication of its own Regulatory Notice soliciting comments on a rule proposal prior to its submission to the SEC.[3] If FINRA decides to issue a Regulatory Notice soliciting public comment on a proposal, the comment period typically is open for one to two months.[4] All comments become part of FINRA's ''official record'' of the rule proposal, and since December 1, 2003, FINRA has posted all comment letters on its website.[5] Depending on the comments received in response to the Regulatory Notice and any changes made to the proposal, FINRA staff will either return to the FINRA Board with a revised proposal or will file the rule proposal with the SEC for notice and comment.[6] Soliciting comments, as FINRA does, in advance of submitting any proposed rules or modifications to the Commission would benefit both the Authority, the regulated community, and the Commission. It would provide transparency and enable the Authority to resolve any issues with its rules prior to their submission to the Commission.

If public comments are solicited, the Commission is requiring the Authority to attach, as an exhibit to its submission under § 1.142, a copy of the comments. The Commission encourages the Authority to make such comments publicly available on its own website. In

[2] *See* Letter from Senator Mitch McConnell to Acting Chairwoman Rebecca Kelly Slaughter (Mar. 23, 2021) (on file with the Federal Trade Commission).

[3] *See* FINRA Rulemaking process, *https://www.finra.org/rules-guidance/rulemaking-process* (last visited July 9, 2021).

[4] *Id.*

[5] *Id.*

[6] *Id.*

addition, the Authority's draft **Federal Register** document must include a summary of the substance of all comments received and the Authority's written response to all significant issues raised in such comments. This advance resolution of comments will greatly facilitate the process of review of any proposed rules or modifications the Authority submits to the Commission.

IV. Section 1.143—Submissions to the Secretary

This section provides guidance for the Authority when submitting documents to the Secretary of the Commission.

All rule submissions made pursuant to § 1.142 and 15 U.S.C. 3053(a), rate increases which must be reported to the Commission under 15 U.S.C. 3052(f)(1)(C)(iv), or HISA Guidance which must be submitted to the Commission under 15 U.S.C. 3054(g)(2), must be emailed to the Secretary of the Commission at *electronicfilings@ftc.gov*. The subject line of the email must state: ''HISA Rule Submission,'' ''HISA Rate Increase Submission,'' or ''HISA Guidance Submission'' as applicable. This will enable the Secretary to easily identify submissions from the Authority and route them to the appropriate office.

To facilitate Commission review, documents must be organized and sent in a format that will facilitate the submission of documents to the Office of the Federal Register. Except for supporting documentation submitted pursuant to § 1.142(b) (existing standards used as a reference for the development of the proposed rule or modification, and scientific data, studies, or analysis underlying the development of the proposed rule or modification) and copies of public comments submitted pursuant to § 1.142(f), all documents submitted to the Secretary must be in a word processing format. This will enable the Commission to more easily make modifications to **Federal Register** documents, provide feedback on rule text, and draft orders. For organizational purposes, the Commission is requiring submissions with more than one attachment to contain a table of contents in the body of the email with a brief description of each item. The Authority must also provide the contact information for a person on the staff of the Authority responsible for responding to questions from the Commission. To facilitate submissions to the Office of the Federal Register, the Commission is requiring that the Authority's draft **Federal Register** documents follow the relevant format and editorial requirements for regulatory documents in the Office of **Federal Register**'s Document Drafting Handbook, 1 CFR parts 18, 21, and 22. Specifically, draft **Federal Register** documents must contain proper preamble captions and content; state the purpose of, and basis for, the proposed rule or modification; set forth regulatory text, headings, and authority citations; use correct numbering, structure, and amendatory language; and conform to style and formatting established by the Office of the Federal Register and Government Publishing Office (see, specifically, section 2.17 (proposed rules) of the Office of the Federal Register's Document Drafting Handbook).

If a document filed with the Secretary contains confidential information, the Secretary must be so informed, and a request for confidential treatment must be submitted in accordance with 16 CFR 4.9. Filings submitted electronically on or before 5:30 p.m. Eastern Time, on a business day, will be deemed filed on that business day, and all filings submitted after 5:30 p.m. Eastern Time, will be deemed filed on the next business day. This section also provides the Secretary of the Commission may reject a document for filing that fails to comply with the Commission's rules for filing in this section or § 1.142. Finally, if the conditions in this section and § 1.142 have been satisfied, the Commission will publish the proposed rules or modifications in the **Federal Register** for public comment.

V. Section 1.144—Approval or Disapproval of Proposed Rules or Modifications

Section 4(c)(1) of the Act, 15 U.S.C. 3053(c)(1) provides, ''Not later than 60 days after the date on which a proposed rule or modification is published in the **Federal Register**, the Commission shall approve or disapprove the proposed rule or modification.'' In addition, Section 4(c)(2) of the Act, 15 U.S.C. 3053(c)(2), provides ''[t]he Commission shall approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with [ ] this chapter; and [ ] applicable rules approved by the Commission.'' Accordingly, § 1.144 provides the Commission will approve or disapprove a proposed rule or modification by issuing an order within 60 days of the date the proposed rule or modification was published in the **Federal Register** for public comment. The Commission will approve a proposed rule or modification if it finds such proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. Further, a proposed rule or modification will not take effect unless it has been approved by the Commission.

Because these rule revisions relate solely to agency procedure and practice, publication for notice and comment is not required under the Administrative Procedure Act. 5 U.S.C. 553(b).[7]

List of Subjects in 16 CFR Part 1

Administrative practice and procedure.

For the reasons set forth in the preamble, the Federal Trade Commission amends title 16, chapter I, subchapter A of the Code of Federal Regulations as follows:

PART 1—GENERAL PROCEDURES

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 15 U.S.C. 46; 15 U.S.C. 57a; 5 U.S.C. 552; 5 U.S.C. 601 note.

■ 2. Add subpart S to read as follows:

Subpart S—Procedures for Submissions Under the Horseracing Integrity and Safety Act

Sec.

Authority: 15 U.S.C. 3053.

§ 1.140 Definitions.

When used in relation to the Horseracing Integrity and Safety Act, 15 U.S.C. 3051 through 3060, and this subpart—

Act means the Horseracing Integrity and Safety Act, 15 U.S.C. 3051 through 3060.

Breeder means a person who is in the business of breeding covered horses.

Commission means the Federal Trade Commission.

Covered horse means any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State racing commission or the breed governing organization for such horse under 15 U.S.C. 3054(*l*), during the period—

(1) Beginning on the date of the horse's first timed and reported workout at a racetrack that participates in covered horseraces or at a training facility; and

[7] For this reason, the requirements of the Regulatory Flexibility Act are also inapplicable. 5 U.S.C. 601(2), 604(a). Likewise, the amendments do not modify any FTC collections of information within the meaning of the Paperwork Reduction Act. 44 U.S.C. 3501 *et seq.*

(2) Ending on the date on which the Authority receives written notice that the horse has been retired.

Covered horserace means any horserace involving covered horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers.

Covered persons means all trainers, owners, breeders, jockeys, racetracks, veterinarians, persons (legal and natural) licensed by a State racing commission and the agents, assigns, and employees of such persons and other horse support personnel who are engaged in the care, training, or racing of covered horses.

HISA Guidance means Horseracing Integrity and Safety Authority (Authority) guidance issued under 15 U.S.C. 3054(g)(1), which does not have the force of law.

Horseracing anti-doping and medication control program means the anti-doping and medication program established under 15 U.S.C. 3055(a).

Horseracing Integrity and Safety Authority or *Authority* means the private, independent, self-regulatory, nonprofit corporation recognized for purposes of developing and implementing a horseracing anti-doping and medication control program and a racetrack safety program for covered horses, covered persons, and covered horseraces.

Interstate off-track wager has the meaning given such term in Section 3 of the Interstate Horseracing Act of 1978, 15 U.S.C. 3002.

Jockey means a rider or driver of a covered horse in covered horseraces.

Owner means a person who holds an ownership interest in one or more covered horses.

Proposed rule means any rule proposed by the Authority pursuant to the Act.

Proposed rule modification or *modification* means:

(1) Any proposed modification to a rule or proposed rule change; or

(2) Any interpretation or statement of policy or practice relating to an existing rule of the Authority that is not HISA Guidance and would have the force of law if approved as a final rule.

Racetrack means an organization licensed by a State racing commission to conduct covered horseraces.

Racetrack safety program means the program established under 15 U.S.C. 3056(a).

State racing commission means an entity designated by State law or regulation that has jurisdiction over the conduct of horseracing within the applicable State.

Trainer means an individual engaged in the training of covered horses.

Training facility means a location that is not a racetrack licensed by a State racing commission that operates primarily to house covered horses and conduct official timed workouts.

Veterinarian means a licensed veterinarian who provides veterinary services to covered horses.

Workout means a timed running of a horse over a predetermined distance not associated with a race or its first qualifying race, if such race is made subject to the Act by election under 15 U.S.C. 3054(*l*) of the horse's breed governing organization or the applicable State racing commission.

§ 1.141 Required submissions.

The Authority must submit to the Commission any proposed rule, or proposed rule modification, of the Authority relating to—

(a) The bylaws of the Authority;

(b) A list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods;

(c) Laboratory standards for accreditation and protocols;

(d) Standards for racing surface quality maintenance;

(e) Racetrack safety standards and protocols;

(f) A program for injury and fatality data analysis;

(g) A program of research and education on safety, performance, and anti-doping and medication control;

(h) A description of safety, performance, and anti-doping and medication control rule violations applicable to covered horses and covered persons;

(i) A schedule of civil sanctions for violations;

(j) A process or procedures for disciplinary hearings;

(k) A formula or methodology for determining assessments described in 15 U.S.C. 3052(f); and

(l) Any other proposed rule or modification the Act requires the Authority to submit to the Commission for approval.

§ 1.142 Submission of proposed rule or modification.

(a) *Contents of submission.* In order for a submission to qualify as a proposed rule or proposed rule modification under 15 U.S.C. 3053(a), the Authority must submit to the Commission a complete draft of the **Federal Register** document for the proposed rule or proposed rule modification, which includes the text of the rule and a statement of the purpose of, and statutory basis for, the proposed rule or modification (''statement of basis and purpose''). The statement of basis and purpose must contain:

(1) The reasons for adopting the proposed rule or modification.

(2) Any problems the proposed rule or modification is intended to address and how the proposed rule or modification will resolve those problems.

(3) A description of any reasonable alternatives to the proposed rule or modification that may accomplish the stated objective and an explanation of the reasons the Authority chose the proposed rule or modification over its alternatives.

(4) How the proposed rule or modification will affect covered persons, covered horses, and covered horseraces.

(5) Why the proposed rule or modification is consistent with the requirements of the Act and any rules and regulations applicable to the Authority, including the following:

(i) *Anti-doping and medication control program.* When proposing a rule or modification to the horseracing anti-doping and medication control program, the Authority must explain how it considered the factors in 15 U.S.C. 3055, including:

(A) Under 15 U.S.C. 3055(a)(2), the unique characteristics of a breed of horse made subject to the Act by election of a State racing commission or breed governing organization for such horse pursuant to 15 U.S.C. 3054(*l*);

(B) The factors listed in 15 U.S.C. 3055(b); and

(C) The baseline anti-doping and medication control rules identified in 15 U.S.C. 3055(g)(2)(A). For a proposed rule, the Authority must state whether its proposed rule adopts the baseline standards identified in 15 U.S.C. 3055(g)(2)(A). If there is a conflict in any baseline standards identified in 15 U.S.C. 3055(g)(2)(A), the Authority must identify the conflict and state whether the standard it adopted is the most stringent standard. For a proposed rule modification, the Authority must explain whether the modification renders an anti-doping and medication control rule less stringent than the baseline anti-doping and medication control rules described in 15 U.S.C. 3055(g)(2)(A), and state whether the anti-doping and medication control enforcement agency has approved of the change.

(ii) *Racetrack safety program.* When proposing a rule or modification to any rule regarding the racetrack safety program required under 15 U.S.C. 3056(a)(1), the Authority must explain how the proposed rule or modification

meets the requirements in 15 U.S.C. 3056(b). The Authority must explain how it considered and whether it adopted the safety standards in 15 U.S.C. 3056(a)(2). If any horseracing safety standards in 15 U.S.C. 3056(a)(2) were considered but not adopted or were modified, the Authority must explain why it decided not to adopt or why it decided to modify such standard.

(iii) *Other rules.* To the extent the Act requires the Authority to consider any factors or standards not specifically referenced in this section, the Authority must explain whether and how it considered those factors when proposing a rule or modification. For instance, when proposing a civil sanctions rule or modification pursuant to 15 U.S.C. 3057(d)(1), the Authority must explain how the rule or modification meets the requirements of 15 U.S.C. 3057(d)(2).

(6) If written comments were solicited, the Authority's draft **Federal Register** document must include a summary of the substance of all comments received and the Authority's written response to all significant issues raised in such comments.

(7) The date that the Authority proposes for the **Federal Register** to publish its proposed rule or modification.

(b) *Supporting documentation.* The Authority's submission to the Commission required under paragraph (a) of this section must also include copies of the pertinent factual information underlying the Authority's development of the proposed rule or modification, including a copy of existing standards used as a reference for the development of the proposed rule or modification and scientific data, studies, or analysis underlying the development of the proposed rule or modification. Supporting documentation must be attached as exhibits, and each exhibit must clearly identify the proposed rule or modification it supports.

(c) *Redline document for proposed rule modification.* For proposed rule modifications, the Authority must also provide, in a document separate from the **Federal Register** document, a redline version of the existing rule that will enable the Commission to immediately identify any proposed changes.

(d) *Timing of submission.* To qualify as a proposed rule or proposed modification under 15 U.S.C. 3053(a), the Authority's submission must provide the information in paragraphs (a), (b), and (c) of this section at least 90 days in advance of the proposed date for the **Federal Register** to publish a proposed rule or modification for public comment pursuant to 15 U.S.C. 3053(b)(1). The Secretary may waive the 90-day requirement in this section if the Authority demonstrates such waiver is necessary to meet statutory deadlines.

(e) *Conclusory statements and failure to provide requisite analysis.* Information required to be submitted under this section must be sufficiently detailed and contain sufficient analysis to support a Commission finding that a proposed rule or modification satisfies the statutory requirements. For instance, a mere assertion or conclusory statement that a proposed rule or modification is consistent with the requirements of the Act is insufficient. Failure to describe and justify the proposed rule or modification in the manner described in this section or failure to submit the information required by this section may result in the Commission's having insufficient information to make an affirmative finding that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission.

(f) *Public comments.* The Authority is encouraged to solicit public comments on its proposed rule or modification in advance of making a submission to the Commission pursuant to this section. If the Authority solicits public comments, it must attach a copy of the comments as an exhibit to its submission. By soliciting public comments and addressing significant issues raised therein, the Authority facilitates the Commission's review and approval of the Authority's proposed rule or modification.

§ 1.143 Submissions to the Secretary.

(a) *Electronic submission.* All rule submissions under § 1.142 and 15 U.S.C. 3053(a), rate increases that must be reported to the Commission under 15 U.S.C. 3052(f)(1)(C)(iv), or HISA Guidance that must be submitted to the Commission under 15 U.S.C. 3054(g)(2) must be emailed to the Secretary of the Commission at *electronicfilings@ftc.gov*. The subject line of the email must state: ''HISA Rule Submission,'' ''HISA Rate Increase Submission,'' or ''HISA Guidance Submission,'' as applicable.

(b) *Format for submission of proposed rules or modifications*—(1) *Electronic format.* Except for supporting documentation submitted pursuant to § 1.142(b) and copies of comments submitted pursuant to § 1.142(f), all documents submitted to the Secretary must be in a word processing format.

(2) *Table of contents.* Submissions with more than one attachment must contain a table of contents in the body of the email with a brief description of each item.

(3) *Contact information.* The Authority must provide the name, telephone number, and email address of a person on the staff of the Authority responsible for responding to questions and comments on the submission in the body of the email.

(4) *Draft* ***Federal Register*** *documents.* Draft **Federal Register** documents must follow the relevant format and editorial requirements for regulatory documents under 1 CFR parts 18, 21, and 22 (see Office of Federal Register's Document Drafting Handbook). The Document Drafting Handbook specifies that draft **Federal Register** documents (see 1 CFR 15.10) must:

(i) Contain proper preamble captions and content;

(ii) State the purpose of, and basis for, the proposed rule or modification;

(iii) Set forth regulatory text, headings, and authority citations;

(iv) Use correct numbering, structure, and amendatory language; and

(v) Conform to the style and formatting established by the Office of the Federal Register and Government Publishing Office. (See, specifically, section 2.17 (proposed rules) of the Office of the Federal Register's Document Drafting Handbook.)

(c) *Confidential information.* If a document filed with the Secretary contains confidential information, the Secretary must be so informed, and a request for confidential treatment must be submitted in accordance with 16 CFR 4.9.

(d) *Date of filing.* If the conditions of this section are otherwise satisfied, all filings submitted electronically on or before 5:30 p.m. Eastern Time, on a business day, will be deemed filed on that business day, and all filings submitted after 5:30 p.m. Eastern Time, will be deemed filed on the next business day.

(e) *Authority to reject documents for filing.* The Secretary of the Commission may reject a document for filing that fails to comply with the Commission's rules for filing in this section or § 1.142.

(f) ***Federal Register*** *publication.* If the conditions in this section and § 1.142 have been satisfied, the Commission will publish the proposed rules or modifications in the **Federal Register** and request public comment on those proposed rules or modifications.

§ 1.144 Approval or disapproval of proposed rules and proposed rule modifications.

(a) *Commission decision.* The Commission will approve or disapprove

a proposed rule or modification by issuing an order within 60 days of the date the proposed rule or modification was published in the **Federal Register** for public comment.

(b) *Standard of review.* The Commission will approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with the Act and the applicable rules approved by the Commission. If the Commission disapproves a rule or modification, it will make recommendations to the Authority to modify the proposed rule or modification within 30 days of such disapproval.

(c) *Effect.* A proposed rule or modification will not take effect unless it has been approved by the Commission.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2021–21306 Filed 10–4–21; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA–2018–N–0236]

RIN 0910–AH53

Medical Device De Novo Classification Process

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to establish requirements for the medical device De Novo classification process under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This final rule establishes procedures and criteria related to requests for De Novo classification (''De Novo request'') and provides a pathway to obtain marketing authorization as a class I or class II device and for certain combination products. These requirements are intended to ensure the most appropriate classification of devices consistent with the protection of the public health and the statutory scheme for device regulation. They are also intended to limit the unnecessary expenditure of FDA and industry resources that may occur if devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness are subject to premarket approval. The final rule implements the De Novo classification process under the FD&C Act, as enacted by the Food and Drug Administration Modernization Act of 1997 (FDAMA) and modified by the Food and Drug Administration Safety and Innovation Act (FDASIA) and the 21st Century Cures Act (Cures Act).

DATES: This rule is effective January 3, 2022.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Sergio de del Castillo, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2431, Silver Spring, MD 20993, 301–796–6419.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

This rule establishes new regulations implementing the medical device De Novo classification process under the FD&C Act, which provides a pathway for certain new types of devices to obtain marketing authorization as class I or class II devices, rather than remaining automatically designated as a class III device, which would require premarket approval under the postamendments device classification section of the FD&C Act.

The De Novo classification process is intended to provide an efficient pathway to ensure the most appropriate classification of a device consistent with the protection of the public health and the statutory scheme for device regulation. When FDA classifies a device type as class I or II via the De Novo classification process, other manufacturers do not necessarily have to submit a De Novo request or premarket approval application (PMA) to legally market a device of the same type. Instead, manufacturers can use the less burdensome pathway of premarket notification (510(k)), when applicable, to legally market their device, because the device that was the subject of the original De Novo request can serve as a predicate device for a substantial equivalence determination.

B. Summary of the Major Provisions of the Final Rule

This rule establishes procedures and criteria for the submission and withdrawal of a De Novo request. It also establishes procedures and criteria for FDA to accept, review, grant, and/or decline a De Novo request. While several comments object to sections or subsections of the proposed rule, almost all comments voice support for the objective of the proposed rule: To establish regulations implementing the De Novo classification process. The rule provides that:

- A person may submit a De Novo request after submitting a 510(k) and receiving a not substantially equivalent (NSE) determination.
- A person may also submit a De Novo request without first submitting a 510(k), if the person determines that

Exhibit

C

HORSERACING INTEGRITY AND SAFETY AUTHORITY

Horseracing Integrity and Safety Authority Submits Draft Racetrack Safety Regulations to the Federal Trade Commission

December 6, 2021 (Lexington, KY) - Today, the Horseracing Integrity and Safety Authority (the Authority) formally submitted draft Racetrack Safety regulations to the Federal Trade Commission (FTC) for review, public comment and final approval with an effective date of July 1, 2022.

The draft rules reflect significant work by the Authority's Racetrack Safety Committee and input from a broad range of regulators, experts, other industry stakeholders, and the general public. The rules will establish a national, uniform program including pre-race veterinary inspections, voided claim rules, racetrack surface maintenance, and the gathering of medications, treatment, and injury data.

In addition, the Authority notified the FTC of the Authority's intent to file final draft rules for the Anti-Doping and Medication Control (ADMC) program later in December, prior to the new year. To date, the United States Anti-Doping Agency (USADA) has led the process of authoring draft rules for the program in coordination with the Authority's ADMC Committee, led by Adolpho Birch. As explained in the formal waiver request, the Authority and USADA are continuing to finalize the terms of the agreement under which USADA will operate as the independent enforcement agency for the new rules. The organizations will also continue to evolve and refine the draft ADMC rules to take into account industry and public feedback.

"We are pleased to have submitted the draft Racetrack Safety rules which will make the sport safer for both equine and human athletes and thank the Authority's Racetrack Safety Committee for their hard work," said Charles Scheeler, Chairman of the Authority's Board of Directors. "In addition, we are deeply grateful for the diligence, expertise and leadership of USADA and the ADMC Committee in developing comprehensive draft ADMC rules in a remarkably short period of time. We are also grateful for the feedback we received from all segments of the racing community regarding these draft rules. We look forward to continuing our partnership as we finalize and operationalize new, nationwide regulations to ensure the integrity and safety of the sport."

Please visit hisaus.org and follow the Authority on Twitter and Facebook to keep up with the latest developments.

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MEDIA CONTACT
MacKenzie Smith
202-262-2650
mackenzie.smith@fgh.com

Exhibit

D

Colorado, individually and as trustee of all of the trusts listed; the Bergmann 2011 Irrevocable Trust Under Agreement, Alma F. Bergmann, trustee, both of Bow Mar, Colorado; the Community Property Trusts under the Michael Dean Bergmann and Alma F. Bergmann Declaration of Trust, Alma F. Bergmann and Michael D. Bergmann, as co-trustees, all of Bow Mar, Colorado; Earl L. Wright, Castle Pines, Colorado; Nathan Bergmann and Kelley Bergmann, both of Denver, Colorado; to form the Wright/Bergmann group, a group acting in concert, to retain voting shares of AMG National Corp., Greenwood Village, Colorado, and thereby indirectly retain voting shares of AMG National Trust Bank, Boulder, Colorado.

B. Federal Reserve Bank of Minneapolis (Chris P. Wangen, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Scott A. Erickson and Matthew P. Bock, both of Sioux Falls, South Dakota:* To retain voting shares of Leackco Bank Holding Company, Inc., Huron, South Dakota, and thereby indirectly retain voting shares of American Bank & Trust, Wessington Springs, South Dakota.

Additionally, the 2021 Jeffory A. Erickson Irrevocable Trust No. 5 (Erickson Trust 5), the 2021 Jeffory A. Erickson Irrevocable Trust No. 6 (Erickson Trust 6), the 2021 Jeffory A. Erickson Irrevocable Trust No. 7 (Erickson Trust 7), and the 2021 Jeffory A. Erickson Irrevocable Trust No. 8 (Erickson Trust 8), and collectively, the ''New Erickson Trusts'', Matthew P. Bock, as trust protector of the New Erickson Trusts, Scott A. Erickson as investment trust advisor of the New Erickson Trusts and trustee of Erickson Trust 5, 6 and 8, and Jamie L. Brown as trustee of Erickson Trust 7, all of Sioux Falls, South Dakota; to join the Erickson family shareholder group, a group acting in concert, by retaining voting shares of Leackco Bank Holding Company, Inc., and thereby indirectly retaining voting shares of American Bank & Trust.

Finally, the 2021 Preston B. Steele Irrevocable Trust No. 1, the 2021 Preston B. Steele Irrevocable Trust No. 2, and the 2021 Preston B. Steele Irrevocable Trust No. 3, collectively, ''the New Steele Trusts'', Matthew P. Bock, as investment trust advisor and trustee of the New Steele Trusts, and Scott A. Erickson, as trust protector of the New Steele Trusts, all of Sioux Falls, South Dakota; to join the Steele family shareholder group, a group acting in concert, by retaining voting shares of Leackco Bank Holding Company, Inc., and thereby indirectly retaining voting shares of American Bank & Trust.

Board of Governors of the Federal Reserve System, December 30, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–28573 Filed 1–4–22; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[File No. P222100]

HISA Racetrack Safety

AGENCY: Federal Trade Commission.

ACTION: Notice of Horseracing Integrity and Safety Authority (HISA) proposed rule; request for public comment.

SUMMARY: The Horseracing Integrity and Safety Act of 2020 recognizes a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority, which is charged with developing proposed rules on a variety of subjects. Those proposed rules and later proposed rule modifications take effect only if approved by the Federal Trade Commission. The proposed rules and rule modifications must be published in the **Federal Register** for public comment. Thereafter, the Commission has 60 days from the date of publication to approve or disapprove the proposed rule or rule modification. The Authority submitted to the Commission a proposed rule on Racetrack Safety on December 6, 2021. The Office of the Secretary of the Commission determined that the proposal complied with the Commission's rule governing such submissions. This document publicizes the Authority's proposed rule text and explanation, and it seeks public comment on whether the Commission should approve or disapprove the proposed rule.

DATES: If approved, the HISA proposed rule would have an effective date of July 1, 2022. Comments must be received on or before January 19, 2022.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Comment Submissions part of the **SUPPLEMENTARY INFORMATION** section below. Write ''HISA Racetrack Safety'' on your comment and file your comment online at *https://www.regulations.gov* under docket number FTC–2021–0076. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Austin King (202–326–3166), Associate General Counsel for Rulemaking, Office of the General Counsel, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

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Background

The Horseracing Integrity and Safety Act of 2020 [1] recognizes a self-regulatory nonprofit organization, the Horseracing Integrity and Safety Authority, which is charged with developing proposed rules on a variety of subjects. Those proposed rules and later proposed rule modifications take effect only if approved by the Federal Trade Commission.[2] The proposed rules and rule modifications must be published in the **Federal Register** for public comment.[3] Thereafter, the Commission has 60 days from the date of publication to approve or disapprove the proposed rule or rule modification.[4]

The Authority submitted to the Commission a proposed rule on Racetrack Safety on December 6, 2021. The Office of the Secretary of the Commission determined that the proposal complied with the Commission's rule governing such submissions.[5]

Pursuant to Section 3053(a) of the Horseracing Integrity and Safety Act of 2020 (the ''Act'') and Federal Trade Commission Rule 1.142, notice is hereby given that, on December 6, 2021, the Horseracing Integrity and Safety Authority (''HISA'' or the ''Authority'') filed with the Federal Trade Commission (the ''Commission'') the proposed Racetrack Safety rule and supporting documentation as described in Items I, II, III, IV, and X below, which Items have been prepared by HISA, as well as the Appendix. The Commission is publishing this notice to solicit comments on the proposed rule from interested persons.

I. Self-Regulatory Organization's Statement of the Background, Purpose of, and Statutory Basis for, the Proposed Rule

a. Background and Purpose

The Horseracing Integrity and Safety Act of 2020 (''Act'') recognizes that a national uniform set of standards for racetrack safety will apply to a broad range of racetracks with widely varying environments in terms of economic structure, race dates, physical attributes, prevailing weather conditions, and other factors. As such, the Act directs the Horseracing Integrity and Safety Authority (''HISA'' or the ''Authority'') to develop and implement ''training and racing safety standards and protocols taking into account regional differences and the character of differing racing facilities.'' The proposed Racetrack Safety rule utilizes a practical approach to this implementation, recognizing that some practices are already in place or can be put in place immediately, while others will require adequate time and resources to implement.

As directed in Section 3052(c)(2) of the Act, the Authority's Racetrack Safety Standing Committee (the ''Committee'') was constituted and undertook developing a comprehensive proposed rule setting forth a uniform set of training and racing safety standards and protocols. The Committee spent hundreds of hours in reviewing and analyzing existing standards and research, meeting and discussing key human and horse safety and welfare issues. The Racetrack Safety Standing Committee comprises four independent members and three industry members:

Susan Stover from California is an industry director on the HISA Board of Directors and chairs the Racetrack Safety Standing Committee of the Authority. Dr. Stover is a professor of surgical and radiological science at the University of California, Davis and an expert in clinical equine surgery and lameness. Her research investigates the prevalence, distribution and morphology of equine stress fractures, risk factors and injury prevention, as well as the impact of equine injuries on human welfare.

Lisa Fortier is an independent member from New York. Fortier is the James Law Professor of Surgery, Equine Park Faculty Director and associate chair for Graduate Education and Research at the Cornell University College of Veterinary Medicine. Her primary clinical and translational research interests are in equine orthopedic surgery, tendonitis, arthritis and regenerative medicine.

Peter Hester is an independent member from Kentucky. Hester is an orthopedic surgeon specializing in sports medicine and previously worked for equine veterinary surgeon William Reed at Belmont Park.

Paul Lunn is an independent member from North Carolina. Lunn is dean of the College of Veterinary Medicine at North Carolina State University. Previously, he was a professor and administrator at Colorado State University and the University of Wisconsin. Lunn's scholarly interests are in equine immunology and infectious disease.

Carl Mattacola is an independent member from North Carolina. Mattacola is dean of the University of North Carolina, Greensboro School of Health and Human Sciences. Prior to this, he was associate dean of academic and faculty affairs for the College of Health Sciences at the University of Kentucky. Mattacola's research has focused on neuromuscular, postural and functional considerations in the treatment and rehabilitation of lower extremity injury.

Glen Kozak is an industry member from New York. Kozak is senior vice president of operations and capital projects for the New York Racing Association's (NYRA) facility and track operations, which include Belmont Park, Saratoga Race Course, Aqueduct Racetrack and others. Prior to joining NYRA, Kozak worked for the Maryland Jockey Club as vice president of facilities and racing surfaces.

John Velazquez is an industry member from New York. Velazquez is one of the most accomplished and respected jockeys in the history of horse racing, having won almost 6,250 races. He is North America's all-time leading money-earning jockey and holds the record for most graded stakes wins. He is a board member of the Permanently Disabled Jockeys' Fund and co-chairman of the Jockeys' Guild. He was inducted into the National Museum of Racing and Hall of Fame in 2012.

Beginning in September 2021, HISA representatives shared various working drafts with several interested stakeholders for input as the rule proposals were being developed. Those interested stakeholders included: Racing Officials Accreditation Program; Racing Medication and Testing Consortium (Scientific Advisory Committee); Water Hay Oats Alliance; National Thoroughbred Racing Association; The Jockey Club; The Jockeys' Guild; Thoroughbred Racing Association; Arapahoe Park; Grants Pass Downs; Arizona Downs; Colonial Downs; Association of Racing Commissioners International (Model Rules Committee); California Horse Racing Board; Kentucky Racing Commission; Delaware Racing Commission; Maryland Racing Commission; National Horsemen's Benevolent and Protective Association; Thoroughbred Horsemen's Association Mid-Atlantic Safety Coalition; Thoroughbred Owner's and Breeders Association; Kentucky Thoroughbred Association; American Association of Equine Practitioners; American Veterinary Medical Association; North American Association of Racetrack Veterinarians; Thoroughbred Safety Coalition; New York Racing Association, Stronach Racing Group (5 Thoroughbred racetracks); Churchill Downs (6 Thoroughbred racetracks); Breeders' Cup; Keeneland; and Del Mar.

[1] 15 U.S.C. 3051 through 3060.

[2] 15 U.S.C. 3053(b)(2).

[3] 15 U.S.C. 3053(b)(1).

[4] 15 U.S.C. 3053(c)(1).

[5] 16 CFR 1.140–1.144; *see also* Fed. Trade Comm'n, Procedures for Submission of Rules Under the Horseracing Integrity and Safety Act, 86 FR 54819 (Oct. 5, 2021).

Additionally, videoconferences were conducted with all state racing commissions (except Arkansas), and a number of industry organizations.

Likewise, prior to finalization of the submissions by HISA to the Commission, working drafts of proposed regulations were made available to the public for review and comment on the HISA website at *https://www.hisausregs.org/.* The website received 1,864 unique visitors, 3,097 total visits, 162 registered users, 137 regulation downloads, and 360 comments. All submitted comments were catalogued by HISA.

With the review, input, and ultimate approval of the Authority's Board of Directors, the proposed Racetrack Safety rule would: (1) Put in place a mandatory national accreditation program for racetracks that utilizes the best practices developed to date for the safety and welfare of racehorses and human participants in horse racing and training; (2) set forth comprehensive record retention and data collection programs to aid HISA in further analysis, research and education on racetrack safety issues for purposes of continuous improvement based on the best empirical evidence available; and (3) establish specific restrictions, requirements and prohibited practices to address key health and safety issues in a uniform manner that can be implemented and enforced immediately in all racing jurisdictions and venues.

b. Statutory Basis

The Horseracing Integrity and Safety Act of 2020, 15 U.S.C. 3051 through 3060.

II. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule

a. Rule Series 2100—Racetrack Safety Accreditation Program

The proposed rule submitted by the Authority would establish a mandatory national accreditation program for all U.S. racetracks that conduct Covered Horseraces (as defined in the Act).

Existing Standards

In developing the mandatory national accreditation program, HISA considered and relied heavily on the substantive provisions of the National Thoroughbred Racing Association Safety and Integrity Alliance Code of Standards (''NTRA Code of Standards''), as directed by the Act. The NTRA Safety and Integrity Alliance (''Alliance''), comprising the largest tracks and horsemen's groups in the U.S. and Canada, was developed to function as a certification/accreditation body for the purpose of recognizing and incentivizing compliance by all stakeholders. Since its inception, the Alliance has helped spearhead reforms in the areas of improved medication and testing policies, guidelines for injury reporting and prevention, safety research, providing a safer racing environment, and post-racing care for retired racehorses. The Alliance reports that through its initiatives there has been a 29.5% drop in the rate across all surfaces since 2009. The NTRA Code of Standards has been maintained and updated based on in-the-field findings, consultation with regulators and industry participants, and collaboration with other industry organizations focused on safety and integrity. A broad-based Alliance Advisory Board as well as the NTRA Board of Directors approve updates to the Code of Standards. Twenty U.S. racetracks have been granted full Safety and Integrity accreditation under the NTRA program.

In developing the national accreditation program set forth in the proposed rule, HISA relied, in part, on the 2021 NTRA Code of Standards (Exhibit 1). The NTRA Code of Standards incorporates many of the specific standards and protocols set forth in the Association of Racing Commissioners International's Model Rules of Racing (''ARCI Rules'') (Exhibit 2). The ARCI ''Model Rules'' of racing and wagering are recognized worldwide as a standard for the independent and impartial regulation of horse racing as well as the conduct of pari-mutuel wagering. Relying on the collective expertise of regulatory personnel in member jurisdictions in consultation with regulated entities, industry stakeholders, fans and individuals, ARCI committees consider ways to improve and enhance the regulation of racing. In some racing jurisdictions, the Model Rules have the force of law as they have been adopted by reference statutorily or through a regulatory rule making. In others they form the basis on which rules are written ensuring substantial uniformity in the regulation of the sport. HISA prepared a comparison of the substantive terms of the proposed rule with various safety standards and provisions of the NTRA Code of Standards and the specific ARCI Rules (Exhibit 3). In addition to these existing standards, HISA also considered and relied on the International Federation of Horseracing Authority's International Agreement on Breeding, Racing, and Wagering (Exhibit 4) and the British Horseracing Authority's Equine Health and Welfare Program (Exhibits 5–7).

1. Rule 2110 *et seq.*—Accreditation Process

The Accreditation process allows the Authority to take into account the regional differences and the character of differing racetracks by providing various levels of accreditation and by allowing racetracks adequate time to comply with the accreditation requirements. At its core, the accreditation process creates a collaborative approach between the Authority and the Racetracks that recognizes all the requirements of accreditation cannot be fully implemented as of the Program Effective Date. A Racetrack that has already been accredited by the National Thoroughbred Racing Association is granted interim Racetrack Safety Accreditation. All other Racetracks are granted provisional Racetrack Safety Accreditation. The initial designations of interim and provisional Racetrack Safety Accreditation last at least until the Committee completes an accreditation assessment under the regulations. The accreditation assessment will evaluate whether a subject racetrack is in compliance with the accreditation requirements in the Rule 2100 Series. If the accreditation assessment concludes that the applicable Racetrack has not reached full compliance with the accreditation regulations, the Committee may grant provisional accreditation for one year and may extend such provisional accreditation if the subject racetrack is undertaking good faith efforts to comply with the accreditation requirements and achieve Accreditation.

2. Rule 2120 *et seq.*—Accreditation Requirements

i. Rule 2121—Racetrack Safety and Welfare Committee

Accreditation requires injury assessment and risk management protocols be in place to investigate equine and human injuries, to identify contributing factors, to educate participants, and to identify risk prevention and risk management measures to reduce the incidence/prevalence of injuries. These requirements are designed to enhance a culture of safety at the racetrack and thus improve safety for covered persons and covered horses. Injury incidence/prevalence will be reduced for the racetrack and racing commission. Racehorse attrition due to injury will be

reduced, maintaining racehorse inventory.[6]

ii. Rule 2130 *et seq.*—Required Safety Personnel: Safety Director

The proposed rule designates an individual that is responsible for overseeing risk assessment, risk management, and interacting with the Authority for Racetrack Safety Accreditation compliance. The proposed rule creates a position that establishes a reporting structure between the Authority and the State Racing Commissions who have entered into agreements with the Authority. This structure also enables coordination of risk assessment and risk management between the State Racing Commissions and the Authority, and thus standardizes risk assessment and risk management among the State Racing Commissions. Covered persons and covered horses will benefit from risk assessment, risk management, and development and implementation of strategies to mitigate future risk, thus creating a safer training and racing environment. Racetracks and racing commissions will benefit from fewer injuries, lower racehorse attrition, and enhanced social license to operate. The position of Safety Director is patterned after existing positions of ''Equine Medical Director'' in several racing jurisdictions including California, Kentucky, Maryland, New York, Virginia, and West Virginia. The position has expanded oversight (in addition to equine safety) of racetrack safety and safety of personnel working with horses.

Likewise, the proposed rule: (1) Designates that current stewards in jurisdictions having an agreement with the Authority will also enforce the Authority Regulations; (2) describes the duties and responsibilities of a Safety Officer who will oversee safety of the barn area, oversee safety protocols, and participate in the Safety and Welfare Committee; and (3) describes the duties and responsibilities of the Regulatory Veterinarian. The proposed rule is intended to ensure that specific individuals have designated responsibilities for creating a culture of safety by overseeing safety in the barn area, contributing to risk assessment and risk management, enforcing Authority regulations, and overseeing racehorse safety.[7]

iii. Rule 2140 *et seq.*—Racehorse Inspections and Monitoring

Rules 2141–2142—Racehorse Veterinary Inspections and Assessments

The rule requires that racehorses are screened and inspected by regulatory veterinarians at several times (opportunities) to detect horses that are unsound, injured or medically compromised. The purposes are to identify at-risk horses and prevent exacerbation of the condition by preventing racing while the horse is compromised, alert the trainer so an affected horse can be appropriately treated and rehabilitated, and detect abuse (*e.g.,* injuries from improper crop use). The rule promotes regulatory veterinarian collaboration with trainers in the appropriate management of racehorses. The proposed rule deters abusive practices such as excessive use of the crop on the racehorse. The rule enhances racehorse welfare by preventing career-ending and catastrophic injuries. The rule enhances jockey welfare because many jockey injuries are the result of racehorse falls from a catastrophic injury during a race. The rule enhances racetrack welfare by reducing racehorse attrition due to career-ending or catastrophic injuries. The rule enhances social perception of racing by preventing catastrophic injuries during racing.[8]

Rule 2143—Racehorse Monitoring

The rule requires that racehorses entering a racetrack be inspected by a veterinarian and determined to be in good health and to have been vaccinated for transmissible and life-threatening diseases. The purpose is to ensure racehorses entering the racetrack are in good health and to prevent transmission of disease by unhealthy racehorses to other racehorses in the racetrack environment. Further, the rule requires that for racehorses leaving the racetrack, information about their intended destination and transporter are provided so that in the case of a disease outbreak contact tracing can occur for disease investigation and containment. The stated ''purpose'' for exiting a racetrack is required for knowledge useful for investigation of medication and training-related factors for racehorse injury and attrition. The rule prevents disease entry and transmission to a dense population of racehorses in racetrack environments and allows for disease investigation and containment in the event of a disease outbreak. The rule also enhances investigations into causes of racehorse injury and attrition by collection of data useful for epidemiological studies. Racehorses travel among racetracks due to the scheduling of race meets at different racetracks throughout a calendar year. Disease prevention and containment are critical to maintaining a healthy racehorse population. The rule optimizes racehorse welfare and prevents closure of racing and racetracks due to a disease outbreak in the racehorse population.[9]

iv. Rule 2150 *et seq.*—Racetrack and Racing Surface Monitoring and Maintenance

The rule requires that racetracks are designed, configured, tested, maintained, and monitored to optimize the racing surface for safety of the racehorse and jockey. Racetracks must be constructed with components that optimize safety of racehorses and human participants. The rule stipulates design criteria for safest known products that are intended to prevent racehorse and jockey injury during training and racing events. The race surface and race surface material are known to influence risk for racehorse injury, and management of the race surface material is known to influence race surface properties. Because the safest design criteria for race surface materials and the effect of management procedures on surface material properties are largely unknown, there is a requirement for data collection to enable studies for association with racehorse injuries. The rule is intended to enhance racehorse welfare by preventing career-ending and catastrophic injuries due to poor race surfaces and preventing accidents due to poor racetrack design and racetrack component design (*e.g.,* starting gate padding). The rule similarly enhances jockey welfare because many jockey injuries are the result of racehorse falls from a catastrophic injury during a race and reducing the severity of jockey accidents by safer racetrack construction (*e.g.,* safety rails). The rule enhances racetrack welfare by reducing racehorse attrition due to career-ending or catastrophic injuries. The rule enhances the social perception of racing by the public by preventing catastrophic injuries during racing.[10]

[6] *See also* Exhibit 8; Exhibit 9 (pages 6–9); Exhibit 10.

[7] *See also* Exhibit 9 (pages 2–3); Exhibit 2 (ARCI–006–015 Stewards); Exhibit 8; Exhibit 2 (ARCI–006–070 Official Veterinarian); Exhibit 11.

[8] *See also* Exhibit 1; Exhibit 2.

[9] *See also* Exhibit 12; Exhibit 13; Exhibit 14; Exhibit 17.

[10] *See also* Exhibit 1; Exhibit 2 (ARCI–007–020, Facilities and Equipment); Exhibit 18 (Surfaces); Exhibit 19 (Racing Surfaces Testing Laboratory website); Exhibit 15.

v. Rule 2160 *et seq.*—Emergency Preparedness

The rule includes accreditation requirements that racetracks adequately undertake various emergency preparedness steps with respect to catastrophic injuries, fire safety, hazardous weather, infectious disease outbreaks and emergency drills. These provisions require racetracks to train emergency response personnel in the types of injuries and situations specific to racetracks. These requirements are intended to ensure racetracks and Covered Persons are adequately prepared to address emergencies in an effective manner if and when they arise. In particular, the rule also specifically provides for a dedicated ambulance to respond to human injuries that occur in the course of training and racing.[11]

vi. Rule 2170—Necropsies

The rule requires that a necropsy (autopsy) be performed on all horses that die or are euthanized at covered racetracks and training centers. The rule also outlines the types of necropsies acceptable to the Authority and unifies necropsy examination protocols and reporting of resultant examinations. Necropsies identify factors that caused or contributed to the horse's death and provide an opportunity to survey racehorses for other injuries. The resulting information will be used to identify abnormalities and implement protective measures to mitigate future injuries. The collected data will be used for research, to make improvements where needed and reduce equine injuries. This information is critical for making associations of causation between racetrack conditions, race and training data and injury. Some racing commissions do not require necropsies or limit them to certain circumstances. Thus, factors that cause racehorses' deaths are not always documented. The regulatory veterinarian will have the responsibilities of establishing the SOP and uploading the resultant necropsy data into the Equine Injury Database.[12]

vii. Rule 2180 *et seq.*—Safety Training and Continuing Education

The first part of the rule requires that participating State Racing Commissions use a uniform national trainer's test as part of the requirements for an individual to be a trainer. The purpose is to have a standardized test among all jurisdictions. The second part of the rule states that persons responsible for racehorse or racecourse management are required to have continuing education for the purpose of enhancing knowledge and conveying new knowledge to industry participants. Implementation of safety and welfare measures relies on the transfer of information known and generated through research to the industry participants that can implement change. Current continuing education opportunities are scarce, variable in quality, non-uniformly applied among jurisdictions, and address only some industry participants. The rule institutes uniform hourly requirements for existing offerings for a greater number of industry participants. Increasing the level of education of industry participants will help ensure that covered persons are familiar with best practices and regulatory requirements governing safety and integrity, promote a culture of safety at the racetrack, enhance safety and welfare of covered horses and covered persons, and increase welfare of the racehorse industry.[13]

viii. Rule 2190 *et seq.*—Jockey Health

The rule will require State Racing Commissions or Racetracks to conduct drug and alcohol testing for jockeys. The rule is intended to help ensure that jockeys are not impaired when riding in a race. Horse racing can be a dangerous sport and it is imperative that jockeys be mentally and physically fit while performing their duties. A jockey that is impaired is a danger to themselves, other jockeys, licensees, and horses.

The rule also requires Racing Commissions or Racetracks to develop protocols for concussion management. A concussion is a type of traumatic brain injury that interferes with normal function of the brain. Continuing to ride is dangerous for the jockey and may cause additional damage/injury. In addition, the impairment creates a dangerous situation for other jockeys and horses.

The rule provides an opportunity to assess a jockey for a possible concussion injury and if detected, reduce the chance of elevating the injury. It also protects other jockeys and horses that may be negatively affected by the injured jockey's impairment. Concussion assessment and requiring clearance for return to the sport from a medical provider are standard practices in most sports prone to concussion injuries. The rule will require that a jockey to be examined and ''cleared'' to return to ride by a qualified medical provider.[14]

b. Rule Series 2200—Specific Rules and Requirements

1. Rules 2220–2230—Attending Veterinarian and Treatment Restrictions

These rules require that only veterinarians licensed by the State Racing Commission can examine, diagnose, and treat racehorses and that the veterinarian is working with the trainer (agent of owner) to appropriately examine, diagnose abnormalities and treat racehorses. The rules are intended to ensure medications and treatments administered to racehorses are given by only veterinarians that have the specific knowledge and expertise to make diagnoses and treat racehorses. Further, the rules require that there is a valid veterinarian-owner/trainer relationship for treatment of racehorses. The rules optimize racehorse care by ensuring that racehorses are appropriately examined by veterinarians specifically knowledgeable about racehorse medicine and surgery, and racing regulations; and that veterinarians and trainers are working collaboratively for optimizing racehorse health.[15]

2. Rule 2240 *et seq.*—Veterinarians' List

The rule establishes a list of horses that have compromised health or unsoundness and prohibits these horses from racing. Further, the rule outlines the process by which the horses are determined to have recovered from their illness or unsoundness and may return to racing. Horses that participate in a race while medically or physically compromised are at risk for exacerbating the illness or physical injury, and in some cases having a career-ending or catastrophic injury, also risking severe injury to the jockey. The rule prevents affected horses from racing until the horses have recovered from their illness or injury. The rule is designed to protect horses from worsening an existing condition, and allow for recovery, rehabilitation, and return to racing in a healthy state. The rule is intended to protect jockeys from injuries associated with falls from horses due to the horse incurring a severe injury during a race and falling at high speed. Racetracks

[11] *See also* Exhibit 2 (ARCI–007–020, Facilities and Equipment); Exhibit 1 (pages 13–17, referring to ARCI standards above); Exhibit 16; Exhibit 15; Exhibit 17.

[12] *See also* Exhibit 10 (Veterinary Practices 1846.5, Postmortem Examination. (a)–(h)); Exhibit 1 (ARCI Model Rules ARCI–011–030 Physical Inspection of Horses, Assessment of Racing Condition, C. Postmortem Examinations(1)–(6)); Exhibit 20; Exhibit 8; Exhibit 9; Exhibit 21.

[13] *See also* Exhibit 1 (referencing ARCI Model Rules ARCI 008–020(A)(4); ARCI 006–015(A), ARCI 006–015(A)); Exhibit 22.

[14] *See also* Exhibit 23; Exhibit 24; Exhibit 25; Exhibit 26.

[15] *See also* Exhibit 1 (pages 42–43, referencing ARCI–011–10); Exhibit 2 (ARCI Model Rules of Racing—ARCI–011–010 Veterinary Practices).

will benefit from the prevention of horse fatalities during races. Racetracks and Racing Commissions will benefit because the Veterinarians' List will be shared among all Racing Jurisdictions so that horses put on the list at one jurisdiction will be identifiable when the horse moves to another jurisdiction.[16]

3. Rule 2250 *et seq.*—Racehorse Treatment History and Records

The rule requires attending veterinarians and trainers to report all medications, treatments, surgical procedures, and off-racetrack exercise history for all covered horses to the Authority's database. The purpose is to discover high risk practices so that injuries and illnesses can be prevented in the future. Knowledge of medication, treatments, surgical procedures, and off-track exercise history data is necessary to correlate medication, treatments, surgical procedures, and off-track exercise history with risk for injury and illness, so that high risk practices can be discovered, and injuries and illnesses can be prevented in the future. Collection and correlation of the information with data on injuries and illnesses will enhance equine welfare by allowing the development of strategies for injury and illness prevention. Jockey welfare and safety will be enhanced by a decrease in the incidence of horse falls due to injury and associated jockey injuries. Industry welfare will be enhanced by lower racehorse attrition. The Authority will develop technology (*e.g.,* tablet apps) to minimize the burden on covered persons.[17]

4. Rule 2260 *et seq.*—Claiming Races

Claiming races are races in which horses entered in the race may be purchased for the claiming price by a new trainer/owner. The horse becomes the property of the new trainer/owner as soon as the horse leaves the starting gate in the race. The rule provides the exceptions that, if the horse dies, is euthanized, is vanned off (due to the inability of the horse to exit the racecourse), becomes unsound or medically compromised, bleeds from the nostrils (and presumably the lungs) after the race, or has a positive drug test, transfer of the horse does not occur. The rule protects the purchaser of the horse from acquiring an injured, compromised, or dead horse. The rule provides disincentives to a trainer/owner to enter a horse compromised from latent injury or ailment in a race with the intent for another trainer/owner to take responsibility by claiming the horse in the race. The option for the claim not to be voided by the potential new trainer/owner is useful in circumstances in which a compromised horse may be rehabilitated after the race, or where the new trainer/owner desires to acquire a horse for breeding purposes as opposed to continuing to train and race. The Waiver Claim Option also allows a horse trainer/owner that rehabilitated a horse and wishes to start the horse in a race to start the horse in a claiming race without the possibility of the horse being claimed by another trainer/owner. This allows a horse trainer/owner to take time to rehabilitate a horse and allow them to then start the horse in a race without the possibility of losing the horse to another trainer/owner. The rule incentivizes trainers/owners to rehabilitate horses for long term health and an extended racing career.

In the case of a successful claim (horse purchase) the rule effects transfer of medical records to the new trainer/owner. Knowledge of medical history provides information to the new trainer/owner so the horse may be managed appropriately, given its history, and obtain the best training and medical care for the horse's optimal health.

The rule protects covered horses from being raced when they are not physically or medically fit to do so. The rule protects covered persons from purchasing a compromised horse. Racetracks, racing commissions, and the racing industry benefit because compromised horses in races are more likely to suffer a catastrophic injury; thus, some catastrophic or career-ending injuries are prevented.[18]

5. Rule 2270 *et seq.*—Prohibited and Restricted Practices

i. Rule 2271—Prohibited Practices

The rule regulates the use of practices that either: (1) Mask pain to allow horses to train and race with injuries or joint disease (*e.g.,* neurectomy, shock wave therapy, electrical medical devices); (2) induce inflammation and pain with the intent to speed healing of injured structures (*e.g.,* thermocautery); or (3) cause pain to stimulate a horse to run faster (*e.g.,* electrical shock). Certain specific practices (such as shock wave therapy) are also addressed in specific rules in this section. The rule is intended to prevent abuse of racehorses by preventing the masking of pain that allows horses to train and race while injured, and by preventing the stimulation of pain to coerce racehorses to perform beyond their athletic potential. Inhumane and dangerous practices on racehorses will be prevented.[19]

ii. Rule 2272—Shock Wave Therapy

The rule regulates the use and monitoring of a treatment (shock wave therapy) used on bone, tendon, and ligament injuries. Shock wave therapy can also provide pain relief that allows affected horses to continue to train and race on a mild injury. Continued training and racing on a mild injury could precipitate a career-ending or catastrophic injury. The rule addresses the problem by closely monitoring treatments and requiring treated horses to refrain from training at high speed or racing until an appropriate time for rehabilitation of the injury that was treated. The rule enhances safety of covered horses by reducing the incidence of career-ending and catastrophic injuries. Because jockey injuries are associated with horse falls due to catastrophic injuries during high-speed training and racing, the rule also enhances jockey safety and welfare.[20]

iii. Rules 2273–2275—Devices

The rules prohibit the use of any device meant to alter the speed or performance of a horse. The rules are in place in all U.S. racing jurisdictions. The penalty for noncompliance is not standard across jurisdictions and varies from a 10-year loss of racing license to suspensions and fines. The rules are intended to standardize the language nationally and standardize sanctions. Stewards will have national standardized language and sanctions when adjudicating cases and issuing sanctions. Covered Persons will know the industry considers use of performance-affecting devices a serious issue.[21]

iv. Rule 2276—Horseshoes

The rule limits the height of rims used as traction devices on forelimb and hindlimb horseshoes. The rule prohibits use of any other traction devices. Traction devices have been thought to

[16] *See also* Exhibit 2 (ARCI–011–030 Physical Inspection of Horses, B. Veterinarians' List; Exhibit 9 (pages 20–21); Exhibit 1 (Section E).

[17] *See also* Exhibit 1 (NTRA Safety & Integrity Alliance—Code of Standards 2021, Trainer Records and Reporting, page 21); Exhibit 2 (ARCI–008–020 Trainers); Exhibit 9 (''Layoff Report''); Exhibit 10 (Rule Nos. 1842, 1842.1, 1842.5).

[18] *See also* Exhibit 27; Exhibit 9 (pages 16–18).

[19] *See also* Exhibit 1 (Shock Wave Therapy, page 20); Exhibit 2 (ARCI Model Rules of Racing ARCI–011–015(4) (shock wave therapy), ARCI–006–020, ARCI–010–030, ARCI–024–025 (heel nerving), ARCI–011–015 (prohibited practices)).

[20] *See also* Exhibit 1 (page 20); Exhibit 2 (ARCI–011–015 Prohibited Practices).

[21] *See also* Exhibit 2 (ARCI–010–035 Running of the Race E(7)(c)—Use of Riding Crop); Exhibit 4.

increase a horse's ability to ''dig in'' to the track surface and prevent slipping. Traction devices reduce the horse's ability to plant its hoof properly and move correctly through the surface. That reduction of movement contributes to catastrophic breakdowns and skeletal and muscle-related injuries. The rule follows the scientific evidence that shows that traction devices increase equine injuries. The rule is intended to increase the safety of covered riders and covered horses by reducing the number of accidents resulting from injuries associated with the use of traction devices. Lower racehorse attrition will enhance racetrack welfare by having greater racehorse inventory to fill races, larger race fields, and consequently greater parimutuel betting. The rule will standardize traction device use nationwide.[22]

6. Rule 2280 *et seq.*—Use of Riding Crop

Allowing use of the crop is critical for the safety of horses and riders. The rule limits the number of times the crop can be used for encouragement. The rule unifies crop design and use of the crop across all jurisdictions. The rule unifies penalties for crop abuse or use of prohibited devices across jurisdictions. There has been heated debate about use of the riding crop, especially for encouragement. Some believe the new crops do not hurt the horse at all, while others remain concerned about the public perception of using a crop for encouragement. The rule allows riding crop use for safety of the horse and jockey. It also limits the number of times the crop can be used for encouragement during a race. This compromise of use of the crop for safety, and limited use for encouragement that will be unified across racing jurisdictions, is in the best interest of the horses, horsemen, the owners, the jockeys, the betting public, racing commissions, and the general public. The rule is intended to protect horses from excessive use of the crop. Jockeys will have a clear understanding of crop use rules and will be able to adapt their usage due to uniformity of the rules.[23]

7. Rule 2290 *et seq.*—Safety and Health of Jockeys

The rule requires that a jockey have a physical examination including baseline concussion testing in order to be eligible to ride in races. Further, the rule states that starting gate personnel and any person mounted on a horse must wear a protective helmet and vest. When mounted on a horse, jockeys must have medical information pertinent to emergency care on their vest. The rule ensures that jockeys are physically fit and capable of riding without endangering other participants during a race. The rule ensures that jockeys and starting gate personnel wear safety vests and helmets to minimize injury in case of an accident. In the case of a jockey injury, medical information pertinent to emergency care will be readily available to medical providers. In the case of a jockey injury, baseline concussion data is available for comparison to the injury-related concussion assessment. Stewards and the Clerk of Scales are responsible for monitoring and reporting non-compliance.[24]

III. Self-Regulatory Organization's Summary of Comments

As encouraged by the Commission's rule, beginning in September 2021, HISA representatives shared various working drafts with several interested stakeholders for input as the rule proposals were being developed. Those interested stakeholders included: Racing Officials Accreditation Program (''ROAP''); Racing Medication and Testing Consortium (Scientific Advisory Committee) (''RMTC''); Water Hay Oats Alliance (''WHOA''); National Thoroughbred Racing Association (''NTRA''); The Jockey Club; The Jockeys' Guild; Thoroughbred Racing Association (''TRA''); Arapahoe Park; Grants Pass Downs; Arizona Downs; Colonial Downs; Association of Racing Commissioners International (Model Committee) (''ARCI''); California Horse Racing Board; Kentucky Racing Commission; Delaware Racing Commission; Maryland Racing Commission; National Horsemen's Benevolent and Protective Association; Thoroughbred Horsemen's Association Mid-Atlantic Safety Coalition; Thoroughbred Owners and Breeders Association; Kentucky Thoroughbred Association; American Association of Equine Practitioners; American Veterinary Medical Association; North American Association of Racetrack Veterinarians; Thoroughbred Safety Coalition; New York Racing Association, Stronach Racing Group (5 Thoroughbred racetracks); Churchill Downs (6 Thoroughbred racetracks); Breeders' Cup; Keeneland; and Del Mar. Additionally, videoconferences were conducted with all State racing commissions (except Arkansas), and a number of industry organizations.

Likewise, prior to finalization of the submissions by HISA to the Commission, working drafts of proposed regulations were made available to the public for review and comment on the HISA website *https://www.hisausregs.org/.* The website received 1,864 unique visitors, 3,097 total visits, 162 registered users, 137 regulation downloads, and 360 comments. All submitted comments were catalogued by HISA and were submitted to the Commission herewith.

The primary areas of the Racetrack Safety Rule that received comments were with regard to Safety and

[22] *See also* Exhibit 28 (In a study of 201 Thoroughbred racehorses that died during racing or training at California racetracks, toe grabs were identified as possible risk factors for fatal musculoskeletal injury, fetlock suspensory apparatus failure, and fetlock condylar fracture. The odds of fatal musculoskeletal injury, fetlock suspensory apparatus failure, and fetlock condylar fracture were 1.8, 6.5, and 7.0, respectively, times greater for horses shod with low toe grabs than for horses shod without toe grabs on front shoes. Horses shod with regular toe grabs on front shoes had odds 3.5, 15.6, and 17.1 times greater ($P < 0.05$) for fatal musculoskeletal injury, fetlock suspensory apparatus failure, and fetlock condylar fracture, respectively, compared with horses shod without toe grabs. The odds of horses shod with rim shoes were a third ($P < 0.05$) of those shod without rim shoes for either fatal musculoskeletal injury or fetlock suspensory apparatus failure.); Exhibit 29; Exhibit 30 (The results supported the hypothesis that using studs will decrease foot slip distance in horses cantering on a grass surface.); Exhibit 31 (A marginal association ($p=0.08$) was detected between moderate ligamentous suspensory apparatus injury and height of toe grab. Toe grab height may remain a risk factor for suspensory apparatus failure and condylar fracture because moderate ligamentous suspensory apparatus injury is a risk factor for suspensory apparatus failure and condylar fracture.); Exhibit 32 (Horses that wore low, regular, or Quarter Horse height toe grabs the week of injury had higher odds of having a mild suspensory apparatus injury, compared with horses that did not wear toe grabs that week ($p=0.16$).); Exhibit 33 (Odds of injury in racehorses with toe grabs on front shoes were 1.5 times the odds of injury in horses without toe grabs, but this association was not statistically significant (95% confidence interval, 0.5–4.1).); Exhibit 34 (Although toe grab height was not a significant risk factor in the multivariable or univariable models in the present study, a prior related study, and a Florida study, found the direction of the relationship between toe grab height and injury in both studies was consistent with higher risk with higher toe grabs. Furthermore, toe grab height is associated with the development of mild suspensory apparatus injury, which is a risk factor for suspensory apparatus failure. The use of high toe grabs has decreased in recent years, and variability in toe grab height is associated with 10% to 16% of the variability in exercise variables, perhaps making it more difficult to detect a significant toe grab effect in univariable and multivariable analyses, respectively. It is possible that a toe grab effect is also confounded by other factors; but, in the absence of other known relationships, avoidance of use of high (≥4 mm) toe grabs is still recommended for injury prevention.); Exhibit 35; Exhibit 4 (Article 7, Racing (Shoeing of Racehorses)); Exhibit 2 (ARCI–010–030 (30)); Exhibit 10 (California Rule 1690.1).

[23] *See also* Exhibit 10 (Crop Rule); Exhibit 36; Exhibit 37; Exhibit 38; Exhibit 39; Exhibit 40; Exhibit 41; Exhibit 42; Exhibit 43; Exhibit 44; Exhibit 45; Exhibit 46; Exhibit 47; Exhibit 48; Exhibit 49; Exhibit 50; Exhibit 51; Exhibit 52; Exhibit 53; Exhibit 54; Exhibit 10; Exhibit 55; Exhibit 56; Exhibit 35; Exhibit 57; Exhibit 58.

[24] *See also* Exhibit 1 (pages 22–24); Exhibit 2 (ARCI–007–020 Facilities and Equipment); Exhibit 2 (ARCI–008–030 Jockeys).

Continuing Education (2182); Claiming Races (2260–2262); Veterinarians' List (2142, 2220–2242); Safety and Welfare Committee and Safety Director (2121–2131); Stewards and Safety Officer (2133–2136); Racehorse Treatment History (2250–2253); Prohibited Practices (2271); Medical Director (2132); Racetrack Surfaces, Monitoring and Maintenance (2150–2154); Necropsies (2170); Riding Crops (2280–2281); and Racehorse Treatment History and Records (2250–2253).

The Committee engaged in a continuous review and consideration process as comments were submitted, analyzed, and discussed both internally and with the various stakeholders. Many of the proposed rules received substantial and wide-ranging support, and thus there were few comments suggesting changes. In several instances, significant changes were made in the ongoing rule development and revision process in direct response to comments received. In some instances, the Committee considered comments but elected to maintain the original proposed provisions based on statutory requirements and limitations and/or substantive analysis based on the expertise of the Committee and the supporting documentation it reviewed and considered.

IV. Self-Regulatory Organization's Responses to Comments and Discussion of Alternatives

The following is a description of the primary subjects that received comments and the manner in which the Authority addressed those comments in developing the proposed rule submitted to the Commission, as well as the reasonable alternatives the Authority considered alongside the option ultimately proposed.

Safety and Continuing Education (Rule 2182)

Comments were received from RMTC, ROAP, WHOA, NTRA, and TRA among other individuals. Comments were highly supportive of requiring continuing education, and several comments asked for increased hourly requirements (*e.g.,* Assistant Trainers should have the same requirements as Trainers: 4 hours). Hourly requirements were increased, more categories of covered persons were added to the list of individuals required to have annual continuing education. Requirements were modified to facilitate compliance for existing resources (*e.g.,* Racing Officials have an 8-hour requirements every 2 years instead of annual requirements of 4 hours because the 8-hour requirements are achievable using the ROAP meeting as a resource). Other comments expressed the need to have a centralized resource with quality-controlled content. The Racing Safety Committee concurs, and after the initial Racing Safety rule rollout, plans to engage in development and implementation of a strategic plan that incorporates a centralized resource, funding and development of education resources, and compliance monitoring after the initial Racing Safety rule rollout. The plan will likely build on the ad hoc evolving HorsemenU industry website. Concerns were also raised about funding, which will also be considered next.

Claiming Races (Rule 2260)

The Transfer of Claimed Horse Records had support from several individual regulatory veterinarians whose perspective was to optimize the welfare of horse by providing historical treatments to the new owner of the horse. The Void Claim rule had few comments (and thus wide acceptance). This rule is generally perceived to incentivize trainers to rehabilitate poorly performing horses instead of racing those horses which are at high risk for catastrophic injury. The rule is thought to contribute to the dramatic drop of catastrophic injuries in those racing jurisdictions that implemented a similar rule. Specific comments were related to including a positive medication violation as an additional reason for voiding the claim. The positive medication violation was added to the items that would void a claim. The Waiver Claiming Option, drawn from the void claim rule in existing jurisdictions, is generally accepted and had few comments. This option allows an individual to retain a claimed horse that otherwise meets some of the requirements for a voided claim. The rule allows an individual to retain the horse, usually for non-racing (breeding) purposes. The RMTC, TRA, and individuals collectively commented and provided evidence that the purse to claim price ratio was unrealistic in consideration of the current structuring of purse monies for claiming races. The rule would penalize trainers/owners by dramatically lowering return for racing. The purse to claim price ratio text was removed from the regulations.

Assessment of Racing Condition and Veterinarians' List (Rules 2142, 2220–2242)

Assessment of Racing Condition by veterinary inspections/observations and placement of horses deemed ineligible to race due to unsoundness or medical conditions on the Veterinarians' List are common practices in many jurisdictions and had generally positive support. The numerous comments ranging from individuals to RMTC, CDI, WHOA, KHRC, NYRA, TRA, Mid-Atlantic Group, Oklahoma, and CNL related to specific items in the rules. In general, the first version of the rule was deemed too lax, and the second version of the rule was deemed too specific and not feasible for breeds other than Thoroughbreds (should the other breeds opt to participate under HISA). Further, there is general concern that there are not enough equine regulatory veterinarians for employment to support the rule. The submitted rule contained increased rigor by increasing the times of inspection by a veterinarian, with lesser regulation of the requirements for each inspection. The Authority intends to augment the requirements by distributing a ''Best Practices'' guidance document. Different jurisdictions had different standdown times for reasons to be put on the veterinarians' list—and commented accordingly. The rule, however, standardized standdown times and the requirements for removal from the veterinarians' list and incorporated a mandatory inspection of the horses by the attending veterinarian and trainer to ensure that a veterinarian attested to soundness and good health while facilitating consult and education of the trainer.

Safety Director and Safety and Welfare Committee (Rules 2121–2131)

The Safety Director and Safety and Welfare Committee are a new position and new structure for most racing jurisdictions. Some racing jurisdictions (*e.g.,* California, Mid-Atlantic Group, New York) have an Equine Medical Director which has similar responsibilities as, but fewer than, the Safety Director. The Safety Director and Safety and Welfare Committee are established specifically for Risk Assessment and Risk Management. Comments were received from broad constituencies including the Minnesota Racing Commission, RMTC, Maryland, WHOA, and Colonial Downs. Comments to the first version of the draft rules were largely related to the perception that jurisdictions would be required to hire additional individuals to fill these roles. Later versions of the rules clarified that existing individuals (*e.g.,* Equine Medical Director) could fill these roles and perform the responsibilities. Further, later revisions clarified that jurisdictions could share individuals to fill the roles and responsibilities. Comments also pointed out that some stakeholders did not have representation on the Safety and

Welfare Committee. Additional committee members were included on the Safety and Welfare Committee (*e.g.,* track superintendent) to include broad representation of all stakeholders.

Stewards and Safety Officer (Rules 2133, 2136)

The Stewards and Safety Officer sections went through considerable revisions in response to comments from ROAP, TRA, KHRC, Maryland, RMTC, CNL, NTRA, and CDI. The Racing Safety Committee recognized that the Stewards are largely employed by the racetracks and eliminated regulatory oversight except to only ensure that the Stewards were also responsible for enforcing the Racing Safety regulations (subject to the applicable State Racing Commission electing to enter into an agreement with the Authority). Similarly, the Stewards' List section was deleted largely due to comments from the RMTC, ROAP, and TRA. The Safety Officer, generally a steward, is currently a position at only some racetracks, but is deemed an important position by the Racing Safety Committee; with oversight of general safety procedures including in the barn stable area. The requirement for a Safety Officer was left in the regulations. There was profound disagreement that a Safety Officer only be required at racetracks that held Graded Stakes races. The intent of the Racing Safety Committee was to reduce the burden of having an additional individual on smaller racetracks, but the perception was that only expensive horses mattered. Therefore, the requirement for a Safety Officer was made standard for all racetracks.

Racehorse Treatment History (Rules 2250–2253)

Racehorse treatment history obtained from attending veterinarians and trainers (Responsible Persons) is deemed important by the Racing Safety Committee because of the scientific reports that indicate that intra-articular corticosteroids,[25] non-steroidal anti-inflammatory drugs,[26] exercise history,[27] and return from lay-up (*i.e.,* rest from racing and training) [28] increase the risk for career-ending or catastrophic musculoskeletal injury. This information will be stored in the Authority's database and used for research into associations with lay-up, and career-ending and catastrophic injuries. The Oklahoma Horse Racing Commission has numerous questions regarding the process and outcomes without suggestions. Comments from the Minnesota Racing Commission and ARCI indicated support for the centralization of data, suggested more rigorous reporting requirements (to those in the initial draft regulations), and the usefulness of the data for identifying horses needing additional scrutiny because of possible increased risk for injury. However, there was concern for the cumbersome process and burden on persons required to submit data. The Racing Safety Committee intends to work with the Authority's Technology section to facilitate ease of reporting and provide information back to data providers that will help them locally and incentivize data reporting.

Prohibited Practices (Rule 2271)

Several practices are prohibited because they may alleviate pain, mask signs of injury, or cause inflammation. These practices include shockwave therapy, neurectomy, thermocautery, and electrical medical therapeutic devices. RMTC, Minnesota Racing Commission, Maryland, KHRC, and Oklahoma Horse Racing Commission commented on the rule. Comments were largely related to two items: (1) Differences in regulating use of shockwave machines and stand down times for shockwave and (2) palmar digital neurectomy. The regulation of use of shockwave machines and stand down times were standardized in the rules. At least several racing jurisdictions currently (and historically) allow palmar digital neurectomy as permissible, stating that horses with palmar digital neurectomy can race safely without increased risk for injury. The Racing Safety Committee decided to disallow all neurectomies (including palmar digital neurectomy) on the principle that a procedure that alleviates pain without resolution of the underlying cause should not be permissible.

Medical Director (Rule 2132)

The Medical Director is included in the regulations to oversee the care and organization of medical needs for jockeys. The position was in the first draft of the regulations, removed because the Racing Safety Committee felt it needed more work, and then after further consideration and work, re-inserted the position of Medical Director to the last draft of the regulations. Consequently, while there are few written comments, the Racing Safety Committee has received verbal comments from stakeholders at the Global Symposium of Racing at the University of Arizona, conducted on December 6 and 7, 2020. Racing jurisdictions perceived that they would be required to hire a full-time physician, which is not the intent of the rule. Further, some racing jurisdictions thought they had adequate procedures in place and that the rule was not necessary. The Racing Safety Committee (with 3 members (athletic trainer, jockey, and physician) of a 7-member committee nominated by a separate Nominating Committee) thought it is important to ensure there is a standard minimum of care for jockey and exercise rider health and safety, and that national coordination of efforts would benefit the industry. Further, the Racing Safety Committee requires all racetracks to implement a concussion baseline assessment and evaluation protocol for determining fitness to ride, particularly after a fall or injury. A compromised jockey risks danger to not only him/herself but to other riders and horses in races.

Racetrack Surfaces (Rules 2150–2154)

The original draft of the Safety Regulations required that racetracks engaged in racetrack renovation consider the installation of a synthetic racing surface on the track. This requirement was based on data indicating that catastrophic injury rates for horses are reduced on synthetic surfaces. Several racetracks registered concerns about this provision, citing the cost of installing and maintaining synthetic surfaces, the training required for racetrack personnel in maintaining the surfaces, and the need for consideration of local climate conditions and product availability. The committee concluded that the proper course is to conduct further research and data on racetrack surfaces to guide the development of future regulations. Therefore, the rule as previously developed was removed from the final draft.

Necropsies (Rule 2170)

Necropsy is a critical tool in determining the cause of equine fatalities. The necropsy provisions in the rules are modeled on AAEP

[25] Whitton, et al. Musculoskeletal injury rates in Thoroughbred racehorses following local corticosteroid injection The Vet J 2014;200:71–76.

[26] Dirikolu, et al. Nonsteroidal anti-inflammatory agents and musculoskeletal injuries in Thoroughbred racehorses in Kentucky. J Vet Pharmacol. Therap. 2008;32:271–279.

[27] Anthenill, et al. Risk factors for proximal sesamoid bone fractures associated with exercise history and horseshoe characteristics in Thoroughbred racehorses. Am J Vet Res 2007;68:760–771.

[28] Carrier, et al. Association between long periods without high-speed workouts and risk of complete humeral or pelvic fracture in Thoroughbred racehorses: 54 cases (1991–1994). J Am Vet Med Assoc 1998;212:1582–1587.

guidelines, comments received that highlighted the practical issues faced by racing commissions and racetracks located in areas of the country that do not have laboratory facilities close by, or that are not open seven days per week. In the final draft, the regulations were revised to permit field necropsies when suitable facilities and resources are not available.

Racing Surface Monitoring and Maintenance (Rule 2154)

Racetrack surface monitoring via data collection is critical in identifying factors that contribute to equine injuries. The regulations regarding racetrack surface monitoring and maintenance were significantly influenced by constituent input. Regional differences, number of race days and available staffing differ greatly between racetracks. The Committee considered the input and fine-tuned the requirements to allow for those differences. Comments from racetracks indicated that the collection of data may be burdensome. The Committee therefore reduced the data collection requirements. For example, the original draft required collection of moisture content and cushion depth at four locations at every ⅛ pole; the revision reduced data collection to two locations at every ¼ pole. This section of the rules was also reworked to reduce the specific information to those items most impactful and common to racetracks. The Committee also plans to develop electronic applications that will speed and facilitate the process for the racetracks taking the measurements and increased the number of formats acceptable for submission of the required information. The Committee will produce ''Standard Protocol'' documents to provide guidance for complying with the rule.

Riding Crops (Rules 2280–2281)

The comments received concerning use of riding crops were numerous and ranged from urging that the use of crops be prohibited altogether except for safety and accident avoidance to urging full discretionary use of the crop by the jockey. Numerous regulations of differing character are presently in effect among racing jurisdictions across the country. After much consideration, the Committee settled on a rule that represents a reasonable accommodation of the various comments and concerns expressed. The rule allows unlimited use of the crop for safety of the jockeys and horses in the race, but limited use for encouragement to 6 uses of the crop on the horse. In addition, there were multiple concerns that the penalties for violation of the crop rule were not severe enough to deter violations. Further, comments were received urging the Committee to also incorporate owner and trainer accountability to relieve the jockey from pressure to make excessive use of the crop during a race. Therefore, loss of purse was incorporated in severe violations. Other comments referred to communication with the public when a jockey will ride without a crop in a race. The Committee adopted the recommendation that in addition to announcement at race time that the public would be notified further in advance by posting the information in the official racing program.

Hazardous Weather (Rule 2164)

The initial drafts contained very detailed requirements and protocols concerning fire safety, hazardous weather, and related provisions. Comments from the racetracks indicated many of these areas are already regulated in detail under local and state law. In response, the Committee removed some requirements in favor of requiring racetracks to document and report compliance with the applicable state and local requirements.

Horseshoes (Rule 2276)

Initial draft allowed some usage of toe grabs but, based on significant industry input and considered research and available industry information, ultimately concluded it was prudent and appropriate to totally preclude toe grabs on forelimbs and hind limbs.

Comments That Were Inapplicable

There were some comments that fell outside the jurisdiction of HISA, such as the following, so were not addressed in the proposed regulations. For example, one comment asked about the status of regulating two-year-old breeze up sales. The Act gives HISA authority over Covered Horses. Horses do not become Covered Horses until they have completed their first official work as defined by the Act, thus two-year-old horses offered in sales do not fall under the jurisdiction of HISA.

V. Legal Authority

This rule is proposed by the Authority for approval or disapproval by the Commission under 15 U.S.C. 3053(c)(1).

VI. Effective Date

If approved by the Commission, this proposed rule will take effect July 1, 2022.

VII. Request for Comments

Members of the public are invited to comment on the Authority's proposed rule. The Commission requests that factual data on which the comments are based be submitted with the comments. The exhibits referred to in the Authority's filing, as well as the written comments it received before submitting the proposed rule to the Commission, are available for public inspection at *www.regulations.gov* under docket number FTC–2021–0076.

The Commission seeks comments that address the decisional criteria provided by the Act. The Act gives the Commission two criteria against which to measure proposed rules and rule modifications: ''The Commission shall approve a proposed rule or modification if the Commission finds that the proposed rule or modification is consistent with—(A) this chapter; and (B) applicable rules approved by the Commission.'' [29] In other words, the Commission will evaluate the proposed racetrack safety rule for its consistency with the specific requirements, factors, standards, or considerations in the text of the Act as well as the Commission's procedural rule.

Although the Commission must approve the proposed rule if the Commission finds that the proposed rule is consistent with the Act and the Commission's procedural rule, the Commission may consider broader questions about the health and safety of horses or the integrity of horseraces and wagering on horseraces in another context: ''The Commission may adopt an interim final rule, to take effect immediately, . . . if the Commission finds that such a rule is necessary to protect—(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces.'' [30] The Commission may exercise its power to issue an interim final rule on its own initiative or in response to a petition from a member from the public. If members of the public wish to provide comments to the Commission that bear on protecting the health and safety of horses or the integrity of horseraces and wagering on horseraces but do not discuss whether HISA's proposed rule on racetrack safety is consistent with the Act or the applicable rules, they should not submit a comment here. Instead, they are encouraged to submit a petition requesting that the Commission issue an interim final rule addressing the subject of interest. The petition must meet all the criteria established in the Rules of

[29] 15 U.S.C. 3053(c)(2).
[30] 15 U.S.C. 3053(e).

Practice (Part 1, Subpart D) [31]; if it does, the petition will be published in the **Federal Register** for public comment. In particular, the petition for an interim final rule must ''identify the problem the requested action is intended to address and explain why the requested action is necessary to address the problem.'' [32] As relevant here, the petition should provide sufficient information for the public to comment on, and for the Commission to find, that the requested interim final rule is ''necessary to protect—(1) the health and safety of covered horses; or (2) the integrity of covered horseraces and wagering on those horseraces.'' [33]

VIII. Comment Submissions

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 19, 2022. Write ''HISA Racetrack Safety'' on your comment. Your comment—including your name and your State—will be placed on the public record of this proceeding, including, to the extent practicable, on the website *https://www.regulations.gov.*

Because of the public health emergency in response to the COVID–19 outbreak and the Commission's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website. To ensure that the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write ''HISA Racetrack Safety'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex B), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex B), Washington, DC 20024. If possible, please submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the public record, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not contain sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other State identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential''—as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov*—as legally required by FTC Rule 4.9(b), 16 CFR 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this document and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments it receives on or before January 19, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/siteinformation/privacypolicy.*

IX. Communications by Outside Parties to the Commissioners or Their Advisors

Written communications and summaries or transcripts of oral communications respecting the merits of this proceeding, from any outside party to any Commissioner or Commissioner's advisor, will be placed on the public record. See 16 CFR 1.26(b)(5).

X. Self-Regulatory Organization's Proposed Rule Language

Rule 2000 Series—Racetrack Safety Program

2010 Definitions
2100 Racetrack Accreditation
2110 Accreditation Process
2120 Accreditation Requirements
2130 Required Safety
2140 Racehorse Inspections and Monitoring
2150 Racetrack and Racing Surface Monitoring and Maintenance
2160 Emergency Preparedness
2170 Necropsies
2180 Safety Training and Continuing Education
2190 Jockey Health
2200 Specific Rules and Requirements of Racetrack Safety Program
2210 Purpose and Scope
2220 Attending Veterinarian
2230 Treatment Restrictions
2240 Veterinarians' List
2250 Racehorse Treatment History and Records
2260 Claiming Races
2270 Prohibited Practices and Requirements for Safety and Health of Horses
2280 Use of Riding Crop
2290 Requirements for Safety and Health of Jockeys

2010. Definitions

When used in the Rule 2000 Series:

Act means the Horseracing Integrity and Safety Act of 2020.

Association Veterinarian means a Veterinarian employed by a Racetrack.

Attending Veterinarian means a Veterinarian hired by the Trainer or Owner.

Authority means the Horseracing Integrity and Safety Authority.

Bled means that blood from one or both nostrils of a Horse has been observed after exercise.

Claim means, in the context of a Claiming Race, the purchase of a Covered Horse for a designated amount.

Claiming Race means a Race in which a Horse after leaving the starting gate may be claimed in accordance with the rules and regulations of the applicable State Racing Commission.

Concussion means an injury to the brain that results in temporary loss of normal brain function.

[31] 16 CFR 1.31; *see* Fed. Trade Comm'n, Procedures for Responding to Petitions for Rulemaking, 86 FR 59851 (Oct. 29, 2021).

[32] 16 CFR 1.31(b)(3).

[33] 15 U.S.C. 3053(e).

Covered Horse means any Thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse, beginning on the earlier of:

(1) The date of the Horse's first timed and reported workout at a Racetrack;

(2) the date of the Horse's first timed and reported workout at a Training Facility;

(3) the date of the Horse's entry in a Covered Horserace; or

(4) the date of the Horse's nomination for a Covered Horserace, and ending on the date on which the Authority receives written notice that the Horse has been retired in accordance with the Protocol.

Unless the context otherwise requires, Horse and Covered Horse shall have correlative meanings for purposes of this Rule 2000 Series.

Covered Horserace or *Race* means any horserace involving Covered Horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers.

Covered Persons means all Trainers, Owners, breeders, Jockeys, Racetracks, Veterinarians, and Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such persons and other Horse support personnel who are engaged in the care, training, or racing of Covered Horses.

Groom means a Covered Person who is not an Owner, Veterinarian, Trainer, or assistant Trainer but is involved in the care of a Covered Horse.

Jockey means a rider of a Covered Horse in a Covered Horserace.

Lead Veterinarian means any Veterinarian appointed pursuant to Rule 2134(b).

Medical Director means an individual designated as Medical Director in accordance with the provisions of Rule 2132.

Out-of-Competition means any period which is not during race day.

Owner means a Person or entity who holds an ownership or property interest in one or more Covered Horses.

Person means a natural person or an organization or other entity.

Program Effective Date means July 1, 2022.

Prohibited List means the Equine Prohibited List identifying the Prohibited Substances and

Prohibited Methods means those prohibited methods set forth in the Rule 4000 Series.

Prohibited Substance means any substance, or class of substances, so described on the Prohibited List.

Protocol means the Equine Anti-Doping and Medication Control Protocol set forth in the Rule 3000 Series.[34]

Race Meet means the entire period granted by the State Racing Commission to a Racetrack for the conduct of Covered Horseraces on the Racetrack's premises.

Racetrack means an organization licensed by a State Racing Commission to conduct Covered Horseraces.

Racetrack Safety Accreditation or *Accreditation* means the process for achieving, and the issuance of, safety Accreditation to a Racetrack in accordance with the Rules 2100 through 2193.

Racetrack Safety Committee means the committee established pursuant to 15 U.S.C. 3052(c)(2).

Racetrack Safety and Welfare Committee means the committee established pursuant to Rule 2121.

Regulatory Veterinarian means a Veterinarian employed, contracted, or appointed by a State Racing Commission, Racetrack, or the Authority, who, in addition to other duties, is responsible for monitoring the health and welfare of Covered Horses during Covered Horseraces.

Responsible Person means the individual designated in the registration with the Authority as the Responsible Person in accordance with the following:

(1) For a Covered Horse that has not yet performed its first Workout (or competed in a Race, whichever is earlier), the Responsible Person shall be the Owner of the Covered Horse unless the Horse is in training in another country.

(2) Once in training, the Responsible Person shall be the licensed Trainer for the Covered Horse. The licensed Trainer's designation as the Responsible Person shall be filed with the Authority. The Trainer designation must be kept current with the Authority. Designation transfers must be in writing and on record with the Authority prior to the effective date of the transfer, except for claiming Races in which transfers must be recorded the same day.

(3) If a Covered Horse ceases training for a period of time, the designation may be transferred to the Owner prior to the effective date.

(4) If the Owner is an entity, the managing Owner shall be named.

ROAP means the Racing Officials Accreditation Program.

Safety Director means an individual designated as, and having the responsibilities of, a Safety Director as set forth in Rule 2131.

Safety Officer means an individual designated as, and having the responsibilities of, a Safety Officer as set forth in Rule 2136.

Shock Wave Therapy means extracorporeal shock wave therapy or radial pulse wave therapy.

Starting Gate Person means any individual licensed as an assistant starter or any individual who handles Horses in the starting gate.

State Racing Commission means the regulatory body established or recognized by a State or the Federal government with authority to regulate, approve, or license Covered Persons and Covered Horses.

Trainer means a Person engaged in the training of Covered Horses.

Training Facility means a location that is not a Racetrack that operates primarily to house Covered Horses and conduct Workouts.

Veterinarian means a licensed veterinarian who provides veterinarian services to Covered Horses and who, as a prerequisite to providing veterinarian services to Covered Horses, has registered with the Authority.

Workout means an official timed running of a Covered Horse over a predetermined distance not associated with a Race.

2100. Racetrack Accreditation

2101. General

(a) The Racetrack Safety Committee and the Authority shall oversee Racetrack Safety Accreditation in accordance with the provisions of Rules 2100 through 2193. The Racetrack Safety Committee may also adopt best practices and guidance in accordance with the Act and the rules and regulations promulgated thereunder to provide further guidance to the Racetracks in the Accreditation Process.

(b) All Racetracks are required to seek and meet the requirements of Racetrack Safety Accreditation with the Racetrack Safety Committee in accordance with the provisions of Rules 2100 through 2193.

2110. Accreditation Process

2111. Interim and Provisional Accreditation

(a) Interim Accreditation.

(1) A Racetrack that is accredited by the National Thoroughbred Racing Association as of the Program Effective Date shall be granted interim Racetrack Safety Accreditation, which shall be effective until the later of:

[34] The Commission notes that the 3000 Series and 4000 Series rules have not yet been proposed by the Authority. This and other cross-references to forthcoming rule proposals will be effective if such rules are proposed by the Authority and approved by the Commission under the same process as this proposed rule.

(i) Such time as the Racetrack Safety Committee completes an Accreditation assessment under Rule 2112 with respect to such Racetrack; or

(ii) the time period established by the Authority under Rule 2114(a).

(b) Provisional Accreditation.

(1) A Racetrack that is not accredited by the National Thoroughbred Racing Association as of the Program Effective Date shall be granted provisional Racetrack Safety Accreditation, which shall be effective until the later of:

(i) Such time as the Racetrack Safety Committee completes an Accreditation assessment under Rule 2112 with respect to such Racetrack; or

(ii) the time period established by the Authority under Rule 2114(b).

(2) The Authority may at any time upon reasonable notice require a Racetrack with provisional Racetrack Safety Accreditation to report on its progress in achieving Accreditation. The Authority may request any additional information from the Racetrack necessary to make its determination and may conduct unannounced on-site inspections at any time.

2112. Accreditation Assessment

(a) Upon the initiation of an Accreditation assessment by the Racetrack Safety Committee, the subject Racetrack shall submit or provide access to any relevant information and documentation requested by the Racetrack Safety Committee. The Racetrack Safety Committee may request any additional information and documentation required for the assessment and may propound additional written questions or inquiries to the Racetrack. The Racetrack shall respond in writing to all additional questions and inquiries within 60 days of receipt of any additional questions and inquires.

(b) After review of all information submitted by the Racetrack under of Rule 2112(a), the Racetrack Safety Committee shall conduct an on-site inspection of the Racetrack. The Racetrack Safety Committee shall then prepare a post-inspection report identifying any aspects of the Racetrack's operations that are not in compliance with the requirements of Rules 2100 through 2193.

(c) Within 60 days of the Racetrack's receipt of the post-inspection report under Rule 2112(b), the Racetrack shall respond in writing to the Racetrack Safety Committee setting forth all actions to be taken by the Racetrack to remedy the areas of non-compliance identified in the post-inspection report, and the timeframes necessary for implementation of such remedial actions.

(d) The Racetrack Safety Committee shall assess the Racetrack's response and make a written recommendation to the Authority whether to issue or deny Accreditation or provisional Accreditation of the Racetrack.

2113. Issuance of Accreditation

(a) The Authority shall determine whether a Racetrack is entitled to Accreditation by evaluating compliance with the requirements set forth in Rules 2100 through 2193.

(b) In determining whether to grant, renew, or deny Accreditation to a Racetrack, the Authority shall review all information submitted by the Racetrack and the Racing Safety Committee's recommendation.

2114. Effective Periods of Accreditation

(a) Accreditation.

(1) Accreditation shall be effective for a period of 3 years.

(2) The Authority may modify the Accreditation period to a period of 1 to 7 years if the Authority determines that such modified period will be consistent with the requirements of Accreditation outlined in Rules 2100 through 2193.

(b) Provisional Accreditation.

(1) Provisional Accreditation shall be effective for an initial period of 1 year.

(2) Upon the expiration of the initial 1 year period referenced in paragraph (1) above, provisional Accreditation may be extended for additional 1 year periods if the Authority determines that the subject Racetrack is continuing to undertake good faith efforts to comply with the requirements of Rules 2100 through 2193 and achieve Accreditation.

2115. Annual Reporting

All Racetracks granted Accreditation under these Rules shall participate in ongoing reporting and review to the Racetrack Safety Committee. All accredited Racetracks shall, by December 31 of each calendar year, submit annual reports to the Racetrack Safety Committee demonstrating compliance with all Accreditation requirements.

2116. Suspension and Revocation of Accreditation

(a) An accredited Racetrack that is in material noncompliance with the Accreditation requirements, after having received notice of the noncompliance and been given a reasonable opportunity to remedy the noncompliance, may have its Accreditation suspended by the Authority.

(b) A provisionally accredited Racetrack that is in material noncompliance with the provisional Accreditation requirements, after having received notice of the noncompliance and been given a reasonable opportunity to remedy the noncompliance, may have its provisional Accreditation suspended by the Authority.

(c) A Racetrack under suspension shall not conduct any Covered Horserace.

(d) A suspended Racetrack that fails to remedy the noncompliance in a reasonable time may have its Accreditation or provisional Accreditation revoked by the Authority.

2120. Accreditation Requirements

2121. Racetrack Safety and Welfare Committee

(a) General. The Racetracks in each State shall form a Racetrack Safety and Welfare Committee to review the circumstances around fatalities, injuries, and racetrack safety issues with the goal of identifying possible contributing risk factors that can be mitigated. The Regulatory Veterinarian shall chair the Racetrack Safety and Welfare Committee.

(b) Composition. The composition of the Racetrack Safety and Welfare Committee may vary among jurisdictions, provided that each Racetrack Safety and Welfare Committee shall include, at a minimum, the following:

(1) Regulatory Veterinarian;

(2) Association Veterinarian;

(3) Medical Director;

(4) Safety Officer or steward, subject to the applicable State Racing Commission electing to enter into an agreement with the Authority if such individual is employed by the State Racing Commission;

(5) Horsemen's representative;

(6) Jockey;

(7) Trainer;

(8) racing secretary, and

(9) racetrack superintendent.

(i) The Regulatory Veterinarian shall chair the Racetrack Safety and Welfare Committee.

(ii) If the Safety Director is not a committee member, the Safety Director shall be an ex officio member of the Racetrack Safety and Welfare Committee.

(c) Responsibilities. The Racetrack Safety and Welfare Committee shall be responsible for:

(1) Review of all equine catastrophic injuries and the circumstances surrounding those injuries, including, at a minimum:

(i) Interviews with Trainers, Jockeys, exercise riders, and Attending Veterinarians, and when appropriate, a qualified human health provider;

(ii) examination of past performances, Workouts, pre-race inspection findings, necropsy examination findings, and Trainer and Veterinary treatment records;

(iii) review of Race or training video footage, if applicable;

(iv) review of racetrack surface conditions and weather information;

(v) convening a meeting with connections of the Covered Horse and other interested Persons, including, at a minimum, the Regulatory Veterinarian, Trainer, and Attending Veterinarian, and if applicable, the Jockey, exercise rider, and racetrack superintendent to:

(A) Convey the findings of the review;

(B) acquire additional information useful for developing strategies for injury prevention; and

(C) provide continuing education or continuing education recommendations related to cause of equine injury, if available, to persons related to the applicable Covered Horse;

(vi) evaluation of factors that may have contributed to injuries;

(vii) evaluation of the effectiveness of protocols and procedures for managing the equine injury scenario; and

(viii) developing strategies to mitigate identified factors that may have contributed to the injury.

(2) Review of all environmental factors related to racing and training that may have contributed to human injury occurrences including:

(i) Evaluation of external factors that may have contributed to injuries;

(ii) development of strategies to mitigate identified factors that may have contributed to the injury; and

(iii) evaluation of the effectiveness of protocols and procedures for managing human injury occurrences;

(3) Consideration of Racetrack safety issues brought to the Racetrack Safety and Welfare Committee's attention;

(4) Summary review of all injuries and considerations to review existing practices;

(5) Development of strategies to reduce or mitigate injury occurrences;

(6) Enhancement of the identification of Horses or conditions for which intervention is warranted;

(7) Enhancement of racetrack safety for equine and human participants; and

(8) Preparation and submission of a report that summarizes the findings of the Racetrack Safety and Welfare Committee under this paragraph (c) to the Authority within 60 days of the end of the applicable Race Meet, unless the Racetrack Safety Committee requires earlier submission.

2130. Required Safety Personnel

2131. Safety Director

(a) The Safety Director shall oversee equine safety, racetrack safety, and risk management and injury prevention at each Racetrack in accordance with the provisions of these rules. The Safety Director may at the same time serve in the applicable jurisdiction as a Regulatory Veterinarian or Safety Officer. Subject to the approval of the Racetrack Safety Committee, the Safety Director may be shared within and among jurisdictions.

(b) If the applicable State Racing Commission does not enter into an agreement with the Authority, then the Racetracks in such jurisdiction shall implement the requirements set forth in this Rule, subject to the Racetrack Safety Committee's approval of the individual named as Safety Director.

(c) The Safety Director shall be responsible for:

(1) Creating a culture of safety for Horses, riders, and Racetrack personnel;

(2) Overseeing all aspects of equine safety, racetrack safety, and safety of personnel working with Horses by ensuring that all activities and practices involving the training and racing of Horses at the track meet required safety standards;

(3) Implementing a risk management and injury prevention program under the oversight of the Racetrack Safety Committee;

(4) Providing guidance to Attending Veterinarians on safety issues;

(5) Maintaining and annually reviewing standard operating procedures and protocols;

(6) Coordinating and overseeing emergency drills that include equine injury and starting gate malfunction;

(7) Reporting all equine injuries and fatalities to the Authority within 72 hours of injury; and

(8) Interacting with the Authority concerning Racetrack Safety Accreditation compliance.

2132. Medical Director

(a) The Medical Director shall oversee the care and organization of the medical needs of Jockeys. The Medical Director shall be either a licensed physician or a board-certified athletic trainer. Subject to the approval of the Racetrack Safety Committee, the Medical Director may be shared within and among jurisdictions.

(b) In any jurisdiction where the applicable State Racing Commission does not elect to enter into an agreement with the Authority to establish a Medical Director consistent with this Rule, the Authority shall appoint and employ a Medical Director to serve as Medical Director in that jurisdiction. The Racetracks in the applicable jurisdiction shall reimburse the Authority for all costs associated with the employment of the Medical Director. Such reimbursement shall be shared by the Racetracks in such jurisdiction proportionally by total handle wagered in the applicable State in the prior calendar year.

(c) The Medical Director shall:

(1) Identify professional medical providers and referral networks that are licensed and certified to oversee racetrack emergency services, which may include, hospital affiliations, nursing staff, EMT service and paramedics, internists, surgeons, family practitioners, dentists, athletic trainers, or psychiatrists;

(2) Make medical provider contact information readily available for ease of communication and immediate coordination of care for any medical event;

(3) Report all human injuries to the Authority within 72 hours of injury;

(4) Coordinate and oversee a plan for on-site medical care, including provisions for emergency medical facilities and staffing;

(5) Implement an emergency drill for a rider injury;

(6) Coordinate and oversee a comprehensive plan for transportation of an injured rider to the nearest Trauma Level One or Two facility;

(7) Coordinate and oversee a plan for transportation of an injured rider to the Racetrack's first aid facility;

(8) Ensure compliance with mandatory annual rider physical examination requirements to indicate readiness to ride for Jockeys, and document compliance to the Authority;

(9) Exercise oversight of medical standards, including the minimum criteria for riding fitness;

(10) Certify a rider's fitness to resume riding after any on-track incident that may impair the rider's reflexes, decision-making or ability to maintain control of his or her Horse in a race;

(11) Implement the program for Concussion evaluation, rider exclusion and clearance, and return to ride protocol;

(12) Develop in writing, subject to annual review and revision as necessary, the Racetrack's Emergency Action Plan, which shall include readiness for medical needs of racing participants, workers, and spectators; and

(13) Work with local, State, and Federal regulators to standardize the approach and response to pandemic-related issues among riders, workers, and spectators.

2133. Stewards

(a) In States where the applicable State Racing Commission elects to enter into an agreement with the Authority, the stewards, in addition to their duties under State law, shall enforce the safety regulations set forth in Rules 2200 through 2293.

(b) To qualify for appointment as a steward, the appointee shall meet the experience, education, and examination requirements necessary to be accredited by the ROAP and be in good standing with all racing jurisdictions.

(c) The requirements of Rule 2133 for any steward employed by a State Racing Commission are subject to the applicable State Racing Commission electing to enter into an agreement with the Authority. If the applicable State Racing Commission does not enter into such an agreement, the Racetracks in the jurisdiction shall implement the requirements set forth in Rule 2133, subject to the Racetrack Safety Committee's approval of the individuals named as stewards by the Racetracks. The stewards named by the Racetracks shall enforce only the safety regulations set forth in Rules 2200 through 2293.

2134. Regulatory Veterinarian

(a) The Regulatory Veterinarian shall:

(1) Subject to the provisions of Rule 2134(b), be employed by the State Racing Commission or similar agency having jurisdictional authority;

(2) be licensed to practice in the applicable jurisdiction;

(3) refuse employment or payment, directly or indirectly, from any Owner or Trainer of a Horse racing or intending to race in the jurisdiction while employed as a Regulatory Veterinarian;

(4) refrain from directly treating or prescribing for any Horse within the applicable jurisdiction except in cases of emergency, accident, or injury; and

(5) be trained, and their proficiency verified, in identifying and stabilizing common musculoskeletal injuries.

(b) In any jurisdiction where the applicable State Racing Commission does not elect to enter into an agreement with the Authority to establish a Regulatory Veterinarian consistent with Rule 2134, the Authority shall employ a Veterinarian to serve as the Lead Veterinarian in such jurisdiction. The Lead Veterinarian shall perform all the duties, obligations, and responsibilities of the Regulatory Veterinarian in these regulations. The Racetracks in the applicable jurisdiction shall reimburse the Authority for all costs associated with the employment of the Lead Veterinarian. The reimbursement shall be shared by the Racetracks in the jurisdiction proportionally by total handle wagered in the applicable State in the prior calendar year.

2135. Responsibilities and Duties of Regulatory Veterinarian

(a) The Regulatory Veterinarian shall have the following responsibilities and duties:

(1) Notify the stewards of any Horse deemed unsafe to be raced, or a Horse that it would be inhumane to allow to race;

(2) conduct pre-race inspections on all potential starters on race day;

(3) inspect any Horse when there is a question as to the physical condition of such Horse independent of the Horse's entry status;

(4) be present in the paddock during saddling, on the racetrack during the post parade, and present at the starting gate until the Horses are dispatched from the starting gate for the Race;

(5) scratch any Horse that is, in the opinion of the Regulatory Veterinarian, injured, ill, or otherwise unable to compete due to a medical or health-related condition;

(6) inspect any Horse which appears to be in physical distress during the Race or at the finish of the Race;

(7) provide emergency medical care to Horses injured while racing and effect case transfer to the Attending Veterinarian;

(8) be authorized to euthanize, consistent with the current version of the AVMA Guidelines for the Euthanasia of Animals, any Horse deemed to be so seriously injured that it is in the best interests of the Horse to so act;

(9) report to the Safety Director the names of all Horses euthanized or which otherwise die at the meeting and the reasons therefor;

(10) maintain the Veterinarians' List of Horses ineligible to race and notify the stewards of the identities of all Horses placed on the Veterinarians' List; and

(11) collaborate with the Safety Director, Chief Veterinarian of the State Department of Agriculture, and other regulatory agencies to take measures to control communicable or reportable equine diseases.

(b) If the Regulatory Veterinarian and his or her staff are unable to fulfill any of the duties described in Rule 2135(a), such duties may, at the request of the Regulatory Veterinarian, be performed by an Association Veterinarian. In such case, the Association Veterinarian shall be responsible for adhering to and upholding the rules and regulations of the Authority and the State Racing Commission.

(c) The Regulatory Veterinarian, and any Association Veterinarian exercising duties of the Regulatory Veterinarian as provided in paragraph (b) above, are authorized to:

(1) Access any and all Horses housed on Racetrack grounds regardless of entry status;

(2) perform inspections of any Horse at any time;

(3) observe Horses during training activities and Workouts;

(4) perform pre-Race veterinary inspections and post-Race observations; and

(5) Place a Horse on the Veterinarians' List.

(d) The Regulatory Veterinarian shall have jurisdiction over the Attending Veterinarians within the grounds of the Racetrack and shall review and consult with the stewards, and State Racing Commission regarding the State Racing Commission license applications of Attending Veterinarians, veterinary technicians or assistants, vendors of medical supplies and equipment, and non-Veterinarian health care providers. The authority and responsibilities of the Regulatory Veterinarian under this paragraph (d) shall not be performed by an Association Veterinarian pursuant to Rule 2135(b).

2136. Racetrack Safety Officer

(a) Each Racetrack shall have a Safety Officer to ensure that all activities and practices involving the training and racing of Horses at the Racetrack meet required safety standards and regulatory guidelines. The Safety Officer may also be a steward.

(b) The Safety Officer shall:

(1) Monitor daily stable area activities and practices in the barn area and on the racetrack for compliance with the applicable State Racing Commission safety regulations and the Rules of the Authority;

(2) Conduct pre-Race Meet racetrack safety inspections;

(3) Monitor outrider compliance with Racetrack rules during morning workouts;

(4) Monitor starting gate procedures;

(5) Monitor ambulance and medical personnel protocols for Horses and riders;

(6) Assist Regulatory Veterinarians with follow-up on Horses barred from training or vanned off during training and racing;

(7) Review ship-in and ship-out lists and undertake appropriate investigations;

(8) Conduct random license checks in the stable area;

(9) Conduct random barn inspections to monitor safety and regulatory

compliance, including fire safety regulations;

(10) Conduct random inspections to verify acceptable management, equine husbandry, and veterinary practices;

(11) Advise stewards of all planned and random inspections;

(12) Enforce fire safety rules in the stable area;

(13) Serve as a member or ad hoc member of the Racetrack Safety and Welfare Committee; and

(14) Make recommendations to Racetrack management and racing officials to ensure the welfare of Horses and riders, the integrity of racing, and compliance with applicable horse racing laws and regulations.

2140. Racehorse Inspections and Monitoring

2141. Veterinary Inspections

(a) Veterinary inspections shall be performed by the Regulatory Veterinarians on all Horses entered in a Race. Such inspections shall include the items listed in Rule 2142.

(b) If, prior to starting a Race, a Horse is determined to be unfit for competition, or if the Regulatory Veterinarian is unable to make a determination of racing soundness, the Regulatory Veterinarian shall notify the stewards that the Horse is scratched. Regulatory Veterinarians shall have the unconditional authority to scratch a Covered Horse from a Race.

2142. Assessment of Racing Soundness

(a) Post-entry screening. The Regulatory Veterinarian shall perform post-entry screenings of previous pre-Race inspection findings of entered Horses to identify Horses that may be at increased risk for injury. The Regulatory Veterinarian shall review past performances, lay-ups (more than 60 days without a timed Workout or Race), last 30 days medical history, previous injury and lameness diagnostics, intra-articular corticosteroid injections, previous surgery, and individual Horse risk factors.

(b) Pre-race veterinary inspection. Every Horse entered to participate in a Covered Horserace shall be subjected to inspection by a Regulatory Veterinarian prior to starting in the Race for which it is entered on race day not later than 1 hour prior to scratch time for the Race in which the Horse is to compete.

(1) The Trainer of each Horse or a representative of the Trainer who is knowledgeable about the Horse and able to communicate with the Regulatory Veterinarian must present the Horse for inspection. Horses presented for inspection must have bandages removed, and the legs must be clean and dry. Prior to inspection, Horses may not be placed in ice and no device or substance shall be applied to the Horse that impedes veterinary clinical assessment.

(2) The Regulatory Veterinarian's inspection of each Horse prior to participating in a Race shall include, at a minimum, the following:

(i) Identification of the Horse;

(ii) Ascertainment of the sex of the Horse;

(iii) Performance of an overall inspection of the entire Horse, assessing general appearance, behavior, disposition, posture, and body condition;

(iv) Observation of the Horse jogging in hand, moving toward and away from the Veterinarian so that both hind-end and front-end motion can be evaluated;

(v) Performance of a digital palpation on both distal forelimbs;

(vi) Placement of the Horse on the Veterinarians' List if the Horse does not jog sound or warm up to the Regulatory Veterinarian's satisfaction;

(vii) Visual observation in the paddock and saddling area, during the parade to post, and at the starting gate; and

(viii) Any other inspection deemed necessary by the Regulatory Veterinarian, including Jockey consultation for the Jockey's mount.

(3) A report summarizing the results of a pre-Race inspection under paragraph (a) shall be submitted to the Authority on the day of the inspection.

(c) Post-race assessment. Post-Race visual observations shall be performed by a Regulatory Veterinarian on all Horses leaving the racetrack at the conclusion of every Race.

(1) If a Horse is determined to have Bled or to be physically distressed, medically compromised, injured, or unsound at any time before exiting the racetrack or leaving the test barn, the Horse shall be placed on the Veterinarians' List and the Regulatory Veterinarian shall document post-race inspection findings to the Authority.

(2) If a Horse is determined to have skin lacerations, swellings, or welts that resulted from crop use, the stewards and Attending Veterinarian shall be notified, and the information documented to the Authority.

(d) Training. Regulatory Veterinarians may observe Horses during training activities. Horses deemed physically distressed, medically compromised, injured, or unsound may be placed on the Veterinarians' List and reported to the Authority.

2143. Racehorse Monitoring

(a) All Horses, including stable ponies, entering the Racetrack grounds must have proof of health certificate and required vaccinations, which shall include:

(1) Certificate of veterinary inspection within the prior 5 days or fewer days if high risk situations dictate;

(2) Verification of EEE/WEE/WNV (encephalitides), rabies, and tetanus vaccinations within the prior 12 months;

(3) Verification of Influenza and Rhinopneumonitis vaccinations within the prior 180 days or fewer days if high risk situations dictate; and

(4) Verification of Negative Equine Infectious Anemia (Coggins) Test within the calendar year or in a shorter period of time if high risk situations dictate.

(b) Each Racetrack shall submit the following information to the Authority with respect to each Horse on its grounds:

(1) Horse identification;

(2) Origin of Horse;

(3) Date of entry;

(4) Verification of certificate of veterinary inspection; and

(5) Verification of vaccinations.

(c) Each Racetrack shall submit the following information to the Authority with respect to each Horse leaving its grounds:

(1) Horse identification;

(2) Intended destination;

(3) Reason for departure;

(4) Date of exit;

(5) Vehicle license plate; and

(6) Transporter.

(d) Horses moving interstate must meet the entry requirements of the destination State, the State Racing Commission in the destination State, and the individual Racetracks or Training Facilities to which the horse is being shipped in the destination State.

2150. Racetrack and Racing Surface Monitoring and Maintenance

2151. Data Collection, Recordkeeping and Submission

(a) Racetracks shall have data collection protocols in place to assist in the proper and consistent maintenance of all racing and training surfaces. Racing and training surface testing and maintenance should be performed based on the Racetrack's written standard operating procedures which are reviewed annually and updated as needed. The Racetrack Safety Committee, or its designees, shall develop and annually update a Racetrack Surface Standard Practices Document.

(b) All Racetrack design records, racing and training surface maintenance

records, surface material tests, and daily tests data shall be recorded in a format acceptable to the Authority and shall be submitted to the Authority. Any test results shall be submitted to the Authority within 1 week of the test results.

2152. Testing Methods

Surface test methods and surface material test methods must be documented and consistent with testing standards from internationally recognized standards organizations including ASTM International, American Society of Agricultural and Biological Engineers, or other relevant international standards, and when possible for unpublished standards, methods consistent with those documented by the Racing Surfaces Testing Laboratory.

2153. Racetrack Facilities

The Racetrack facilities must be designed, constructed, and maintained as provided in Rule 2153 to provide for the safety of Covered Persons and Covered Horses.

(a) Rails.

(1) Racetracks shall have inside, outside, and gap rails designed, constructed, and maintained to provide for the safety of Jockeys and Horses.

(2) Objects within 10 feet of the inside rail shall be flexible enough to collapse upon impact of a Horse or rider, or sufficiently padded as to prevent injury.

(3) Rails shall be inspected prior to each Race Meet and daily during training and racing events.

(b) Gaps.

(1) All gaps must be clearly marked, must have protective padding covering any sharp edges or unique angles, and have proper mechanisms to allow for secure closure when needed.

(2) Main gaps and on-gaps should include signage with safety rules, Racetrack hours, and other applicable rules.

(3) For Races breaking from a chute there should be sufficient temporary rail extension to prevent Horses from ducking in or out.

(c) Starting gate.

(1) All gates, and the vehicle that moves the gates, must be inspected pre-Race Meet and documented to be in proper working condition.

(2) All gates must have protective padding to ensure the safety of the Horse, Jockey, and gate personnel. Protective padding shall protect the riders and gate personnel from contact with sharp edges and help to distribute impact loads. All padding shall be designed to ensure durability for outdoor use and shall be capable of maintaining safety and physical integrity during all weather conditions.

(3) Gates and the vehicle that moves the gates shall be inspected and tested each race day before the Races and each morning before schooling to ensure proper functioning.

(4) No personnel, other than those required for steering the gate, shall ride on the gate while the gate is in motion or being transported.

(5) Racetracks shall have in place annually reviewed and documented standard operating procedures for the removal of the starting gate after the start of each Race as needed in a safe and timely manner. This plan shall also include procedures for gate removal if the primary removal mechanism fails.

(6) Every Starting Gate Person shall wear protective gear when working on or around the starting gate, including approved helmets and safety vests.

(7) If the starting gate becomes inoperable during racing hours, racing may not continue until the starting gate is brought back to safe operating standards or the inoperable gate is replaced with a properly functioning alternate gate.

(8) During racing hours, a Racetrack should ensure that sufficient assistant starters are available to safely handle each Horse entered in a Race.

(9) A Racetrack shall make at least one starting gate and one Starting Gate Person available for racehorse schooling during designated gate training hours.

(d) Emergency warning system.

(1) Each Racetrack shall have an operational emergency warning system on all racing and training tracks. The emergency warning system shall be approved by the State Racing Commission, subject to the applicable State Racing Commission electing to enter into an agreement with the Authority. If such agreement does not exist, the emergency warning system shall be approved by the Authority.

(2) The emergency warning system shall be tested bi-weekly before training or racing.

(3) During training, when the emergency warning system is activated, all persons on horseback shall slow to a walk and no one on horseback shall enter the racetrack.

(4) The Racetrack announcer shall be trained to utilize the public address system to:

(i) Warn riders of potentially dangerous situations and provide direction; and

(ii) Warn patrons of potentially dangerous situations and provide direction.

2154. Racetrack Surface Monitoring

(a) Racetracks shall provide equipment and personnel necessary to maintain the racetrack surface in a safe and consistent condition.

(b) Pre-meet inspection shall be performed on all surfaces prior to the start of each Race Meet with sufficient time allotted to facilitate corrections of any issues prior to racing. For Race Meets spanning periods with significant weather variation, inspections shall be performed seasonally prior to anticipated weather changes.

(1) Inspections for dirt and synthetic surfaces shall include the following elements:

(i) Determine and document race and training track configurations and geometries, including:

(A) Geometry and slopes of straights and turns and slopes at each distance marker pole;

(B) The accuracy of distances from the finish line to the marker poles; and

(C) Cushion and base geometries;

(ii) Base inspection, including windrowing and base survey, surface survey, ground penetrating radar, or other method;

(iii) Mechanical properties of racing and training tracks using a biomechanical surface tester shall be determined and documented;

(iv) Surface material samples of racing and training tracks shall be analyzed for material composition pursuant to the Racetrack Surface Standard Practices Document; and

(v) Corrective measures to address issues under paragraphs (i) through (iv) above.

(2) Inspections for turf surfaces shall include the following elements:

(i) Determine and document racetrack configuration and geometry, including:

(A) Geometry and slopes of straights and turns and slopes at each distance marker pole;

(B) irrigation systems;

(C) turf profile; and

(D) ensure distances from the finish line to the marker poles are correct;

(ii) Document turf species;

(iii) Mechanical properties of racing and training tracks using a surface tester should be determined and documented;

(iv) Surface material samples of racing and training tracks shall be analyzed for material composition pursuant to the Racetrack Surface Standard Practices Document;

(v) The irrigation system must be tested to evaluate function of all components and water coverage including gaps and overlap; and

(vi) Corrective measures to address issues under paragraphs (i) through (v) above.

(c) Daily measurements shall be taken at the beginning of all daily training and racing sessions for racing and training tracks, and taken at each ¼ mile marker pole at locations 5 and 15 feet outside the inside rail.

(1) For dirt and synthetic surfaces, such daily measurements shall include:

(i) Moisture content;

(ii) Cushion depth; and

(iii) Weather conditions and precipitation at 15-minute intervals from a national or local weather service.

(2) For turf surfaces, such daily measurements shall include:

(i) Moisture content; and

(ii) Penetration and shear properties.

(d) Surface equipment inventory, surface maintenance logs, and surface material addition or renovation logs shall be maintained and submitted to the Authority.

(1) Daily surface maintenance logs should include equipment used, direction of travel, and water administration.

(2) Documentation of the source, timing, quantity, and method of all additions to the surfaces shall be submitted to the Authority.

2160. Emergency Preparedness

2161. Emergency Drills

Emergency protocols shall be reviewed, and drills shall be conducted, prior to the beginning of each Race Meet for purposes of demonstrating the Racetrack's proficiency in managing the following emergencies:

(a) Starting gate malfunction;

(b) Paddock emergencies;

(c) Equine injury;

(d) Jockey injury;

(e) Loose Horse;

(f) Fire;

(g) Hazardous weather condition; and

(h) Multiple injury scenarios for both Horses and Jockeys.

2162. Catastrophic Injury

Racetracks and Training Facilities under the jurisdiction of a State Racing Commission shall have protocols in place for instances of catastrophic injury to Horses during racing and training. Protocols should include, but not be limited to, requiring collection of biological samples in sufficient volume, to permit comprehensive drug testing. Planning shall include appropriate means of communication to the public.

2163. Fire Safety

Racetracks and Training Facilities under the jurisdiction of a State Racing Commission shall plan for and have protocols in place for instances of fire within their enclosures. Fire and life safety inspections shall be performed in accordance with the local authority and appropriate National Fire Protection Association standards and shall be conducted at the required frequency. Racetracks shall document adherence to the applicable local fire protection authority.

2164. Hazardous Weather

Each Racetrack shall develop, implement, and annually review a hazardous weather protocol which shall include:

(a) Designation of the personnel responsible for monitoring weather conditions, immediately investigating any known impending threat of dangerous weather conditions and determining if conditions exist which warrant delay or cancellation of training or racing and the notification to the public of such dangerous weather conditions;

(b) Use of a designated weather watcher and a reliable source for monitoring the weather, including lightning strike distance/radius notifications;

(c) Implementation of a dangerous weather protocol, which includes for extreme heat and chill factors and air quality;

(d) Designation by the Racetrack of an official responsible for monitoring weather conditions during training and racing hours;

(e) Consideration by the Racetrack of lightning safety guidelines such as the National Athletic Trainers' Association Position Statement, or more recent evidence-based recommendations;

(f) Requirements that the stewards shall contact Racetrack management when weather conditions may become hazardous, and that the stewards shall commence a racing and training delay when weather conditions pose risks to human and equine welfare; and

(g) Designation by the Racetrack of an official responsible for enforcing any weather associated training delay.

2165. Infectious Disease Management

(a) Plans and protocols shall be put in place by each Racetrack to manage an infectious disease outbreak. Such protocols shall be based on guidelines recommended by the AAEP General Biosecurity Guidelines and AAEP Healthy Horse Protocols: Biosecurity Guidelines for Racetrack Entry and Stabling or more recent versions or developed in consultation with the appropriate State agency or official.

(b) The Regulatory Veterinarian shall maintain written biosecurity guidelines and standard operating procedures and train Racetrack safety personnel in basic biosecurity protocols. All Covered Persons must report any symptoms that may be attributed to an infectious disease to the Regulatory Veterinarian and Safety Director.

(c) During an infectious disease outbreak, the above requirements may be revised as dictated by the circumstances, and all Covered Persons shall adhere to disease control measures implemented by State Racing Commissions or applicable State veterinary authorities.

(d) The Safety Director, or Regulatory Veterinarian if the Safety Director is not a licensed veterinarian, must notify the Chief Veterinarian of the relevant State Department of Agriculture (or comparable State government official) to enable timely and accurate reporting of disease outbreaks at the racetrack to the Equine Disease Communication Center.

2166. Human Ambulance Support

(a) A Racetrack shall provide a properly staffed and equipped Advanced Life Support ambulance during training and racing hours. If the ambulance is being used to transport an individual, the Racetrack may not conduct a race, or allow Horses with riders on the racetrack, until the ambulance is replaced or available for service.

(b) Racetracks shall ensure the Advanced Life Support ambulance staff has been trained in Concussion management. Any Jockey who falls or is thrown from a Horse during a race must be examined by the Advanced Life Support staff. Advanced Life Support staff shall report their findings to the stewards who will determine if the Jockey may continue riding.

(c) Unless otherwise approved by the State Racing Commission or the stewards, an ambulance shall follow the field at a safe distance during the running of races.

(d) The ambulance must be parked at an entrance to the racing strip except when the ambulance is being used to transport an individual or when it is following the field during the running of a race.

2167. Accident Reporting System

(a) Racetracks shall develop standard operating procedures for the collection of data associated with all incidents resulting in Jockey or exercise rider injuries sustained at the racetrack and submit such information to the Authority within 10 days of the injury occurrence. Covered Persons involved in, or witnesses to, the circumstances surrounding the injury shall make themselves available to and cooperate with those individuals collecting data for the database.

(b) Data collected shall include:
(1) Name of person injured;
(2) nature of the injury;
(3) date and time of day of injury;
(4) occupation of person;
(5) cause of the incident;
(6) weather;
(7) location of the incident; and
(8) witness statements.

2168. Equine Ambulance

A dedicated Horse ambulance with personnel trained to operate the ambulance shall at all times be available for rapid deployment during racing and training periods. It is recommended that a second ambulance be available in the case of multiple equine injuries or failure of the primary Horse ambulance.

2169. Paddock Safety

Racetracks shall have protocols in place to manage the safety of their saddling paddocks and walking rings. Such protocols should include crowd management policies as well as emergency response procedures for human and equine injuries. An emergency medical technician or paramedic shall be present during saddling.

2170. Necropsies

(a) All Horses that die or are euthanized on Racetrack grounds shall have an autopsy (necropsy) examination performed.

(b) Necropsies should be performed at facilities and by personnel with capabilities and expertise to perform necropsy examination of racehorses. Relationships and contact information shall be included in the necropsy standard operating procedure. The Veterinarian performing the necropsy shall not be an Attending Veterinarian of the affected Horse.

(c) Field necropsy is strongly discouraged. When a field necropsy is the only practical option available, necropsy examinations shall be performed under direct or indirect supervision of a board-certified pathologist including phone call guidance or video conferencing. Necropsies shall be performed in a secure area on all Horses that die or are euthanized on Racetrack premises, isolated from the general public. Whenever possible, the Veterinarian performing the necropsy shall not be an Attending Veterinarian of the affected Horse.

(d) Transportation options for necropsy cases and invoicing for the transportation and necropsy shall be identified prior to need and included in a standard operating procedure. Secure storage, pending transport, and transportation of the body should be managed in such a way that tissue degradation and the development of post-mortem artifacts are minimized. Care shall also be taken to implement sound infection control practices with respect to equine infectious or zoonotic disease.

(e) Gross necropsy examination findings must be submitted by the Regulatory Veterinarian to the Authority within 72 hours of receiving the necropsy report, and updates submitted to the Authority within 72 hours as the results of ancillary tests and the final report are received. This workflow shall be included in the necropsy standard operating procedures.

2180. Safety Training and Continuing Education

2181. Uniform National Trainers Test

Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall require the use of a uniform National Trainers Test in addition to any State licensing requirements. This test shall have a written component and include practical interviews that demonstrate knowledge and proficiency in basic horsemanship skills, knowledge of racing office protocols, State specific information, and basic equine health care.

2182. Continuing Education

(a) Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall identify existing, or provide locally, training opportunities for all Racetrack employees having roles in Racetrack safety or direct contact with Covered Horses.

(b) Required annual continuing education shall include:

(1) Regulatory Veterinarians must complete, on an annual basis, at least 8 hours continuing education specific to racetrack regulatory medicine;

(2) Attending Veterinarians must complete, on an annual basis, at least 8 hours continuing education specifically applicable to racetrack practice;

(3) Medical Directors must complete, on an annual basis, at least 8 hours continuing education;

(4) stewards shall be either accredited or actively participating in gaining accreditation through the ROAP and Certification Programs (maintenance of the ROAP Accreditation requires at least 16 hours of continuing education every 2 calendar years);

(5) Trainers must complete, on an annual basis, at least 4 hours annual continuing education;

(6) assistant trainers must complete, on an annual basis, at least 4 hours annual continuing education;

(7) Owners must complete, on an annual basis, at least 2 hours annually;

(8) Racetrack surface managers must complete at least 8 hours of continuing education every 2 years;

(9) Grooms must complete, on an annual basis, at least 2 hours annual continuing education offered in English and Spanish;

(10) outriders must complete, on an annual basis, at least 2 hours safety and outrider protocol training delivered locally prior to the beginning of a Race Meet;

(11) Jockeys and exercise riders must complete at least 2 hours safety and rider protocols delivered locally in English and Spanish prior to the beginning of a Race Meet;

(12) starters and assistant starters must complete, on an annual basis, at least 2 hours safety training either delivered locally prior to the beginning of a Race Meet or through the ROAP certification; and

(13) Equipment operators must complete, on an annual basis, at least 2 hours safety training either delivered locally prior to the beginning of a Race Meet or through a continuing education program.

2190. Jockey Health

2191. Jockey Drug and Alcohol Testing

Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall develop and implement a testing program for drugs and alcohol for Jockeys. The program shall include provisions for medications prescribed by licensed medical doctors that do not affect mental and physical abilities. If a State Racing Commission does not elect to enter into an agreement with the Authority, the Racetracks in such States shall develop and implement a testing program for drugs and alcohol for Jockeys, subject to the approval of the Authority.

2192. Concussion Management

State Racing Commissions, or Racetracks if the applicable State Racing Commission does not enter into an agreement with the Authority, shall implement a Concussion management program for Jockeys containing the following elements:

(a) Each Jockey shall acknowledge in writing that they have been made aware of the Concussion protocols in place for the facility at which they are riding;

(b) A minimum assessment shall include a current Concussion assessment tool examination;

(c) A return-to-ride guideline shall be established in order to clear a Jockey who has been concussed, or is believed to have been concussed, once the Jockey is declared fit-to-ride; and

(d) The stewards shall be notified when a Jockey is not permitted to ride and when the Jockey has been authorized to return to riding.

2193. Insurance

In States where workers compensation benefits are not afforded to Jockeys by State statute or regulation, Racetracks shall maintain a minimum standard of One Million Dollars ($1,000,000) per incident worth of accident medical expense coverage for all Jockeys.

2200. Specific Rules and Requirements of Racetrack Safety Program

2210. Purpose and Scope

(a) The purpose of Rules 2200 through 2293 is to establish specific safety rules and requirements designed to enhance equine and Jockey safety in Horse racing.

(b) Violation of, or failure to comply with, the requirements of Rules 2200 through 2293 shall result in disciplinary action by racing officials and the Authority.

(c) Safety rules arising under State laws or regulations not preempted by 15 U.S.C. 3054(b) shall be governed by applicable State laws and regulations.

2220. Attending Veterinarian

(a) Only Veterinarians licensed by the State Racing Commission may attend to Covered Horses at any location under the jurisdiction of a State Racing Commission.

(b) Veterinarians attending at any location under the jurisdiction of a State Racing Commission are under the authority of the Regulatory Veterinarian and the stewards.

2221. Treatments by Attending Veterinarian

The following limitations apply to drug treatments by Attending Veterinarians of Covered Horses that are engaged in activities related to racing, including training:

(a) No drug shall be prescribed, dispensed, or administered except in the context of a valid Veterinarian-client patient relationship between a Veterinarian, the Owner (who may be represented by the Trainer) and the Covered Horse. The Owner is not required to follow the Veterinarian's instructions, but no drug may be administered without a Veterinarian having examined the Horse and provided the treatment recommendation. Such relationship requires the following:

(1) The Veterinarian, with the consent of the Trainer (on behalf of the Owner), has accepted responsibility for making medical judgments about the health of the Horse;

(2) the Veterinarian has sufficient knowledge of the Horse to make a preliminary diagnosis of its medical condition;

(3) the Veterinarian has performed an examination of the Horse and is acquainted with the keeping and care of the Horse;

(4) the Veterinarian is available to evaluate and oversee treatment outcomes, or has made appropriate arrangements for continuing care and treatment;

(5) the relationship is maintained by veterinary visits as needed; and

(6) the medical judgments of the Veterinarian are independent and are not dictated by the Trainer or Owner of the Horse.

(b) The Trainer and Veterinarian are both responsible for ensuring compliance with this Rule, except that the medical judgment to recommend a drug treatment or to prescribe a drug is the responsibility of the Veterinarian, and the decision to proceed with a drug treatment that has been so recommended is the responsibility of the Owner (who may be represented by the Trainer or other agent).

2230. Treatment Restrictions

(a) Only Trainers or their designees shall be permitted to authorize veterinary medical treatment of Covered Horses under their care, custody, and control at locations under the jurisdiction of the State Racing Commission.

(b) No person other than a Veterinarian licensed to practice veterinary medicine in the State and licensed by the State Racing Commission may prescribe medication with instructions for administration by a Responsible Person for a Covered Horse.

(c) Attending Veterinarians shall not have contact with an entered Horse within 24 hours before the scheduled post time of the race in which the Horse is scheduled to compete unless approved by the Regulatory Veterinarian, or in an emergency. Any unauthorized contact may result in the Horse being scratched from the race in which it was scheduled to compete and may result in further disciplinary action by the stewards.

(d) The Regulatory Veterinarian may administer emergency treatment to Horses on Racetrack grounds when the Attending Veterinarian is not present.

(e) Except as set forth in paragraph (f) below, no person shall possess a hypodermic needle, syringe capable of accepting a needle or injectable of any kind on racetrack grounds or any facility under the jurisdiction of the Regulatory Authority, unless otherwise approved in writing by the State Racing Commission.

(f) At any location under the jurisdiction of the State Racing Commission, Veterinarians may use only one-time disposable syringes, needles, or IV infusion sets; and shall dispose of items in a manner approved by the State Racing Commission and applicable State and governmental regulations.

(g) If a person has a medical condition which makes it necessary to have a syringe at any location under the jurisdiction of the State Racing Commission, that person may request permission of the stewards or the State Racing Commissioning in writing, shall furnish a letter from a licensed physician explaining why it is necessary for the person to possess a syringe, and shall comply with any conditions and restrictions set by the stewards and the State Racing Commission.

2240. Veterinarians' List

(a) A Veterinarians' List shall be maintained by the Authority of all Horses that are determined to be ineligible to compete in a Covered Horserace in any jurisdiction until released by a Regulatory Veterinarian.

(b) The following Horses shall be placed on the Veterinarians' List until removed in accordance with Rules 2241 and 2242:

(1) Horses affected by illness, physical distress, medical compromise, unsoundness, injury, infirmity, heat exhaustion, positive test or overage, administration of a medication invoking a mandatory stand down time, administration of Shock Wave Therapy, positive Out-of-Competition test or any other assessment or determination by Regulatory Veterinarians that such Horse is unfit to race;

(2) Horses which have not started in more than 365 days; and

(3) Horses which have not made a start prior to January 1 of their 4-year-old year.

(c) Trainers and Owners shall be notified in writing within 24 hours that their Horse has been placed on the Veterinarians' List.

(d) Diagnostic testing may be required for any Horse placed on the Veterinarians' List, at the discretion of

the Safety Director, Regulatory Veterinarian, or Association Veterinarian.

2241. Duration of Stay on the Veterinarians' List

Horses placed on the Veterinarians' List in accordance with Rule 2240 shall remain on the Veterinarians' List as follows:

(a) Horses placed on the Veterinarians' List for unsoundness or Epistaxis shall remain on the list for 14 days;

(b) Horses placed on the Veterinarians' List multiple times for unsoundness within the previous 365 days shall remain on the Veterinarians' List for 45 days for the second time, 75 days for the third time, and shall be barred from further racing after the fourth time;

(c) Horses placed on the Veterinarians' List multiple times for Epistaxis within the previous 365 days shall remain on the Veterinarians' List for 30 days for the second time, 180 days for the third time, and shall be barred from further racing after the fourth time;

(d) Horses placed on the Veterinarians' List for illness shall remain on the list for 7 days;

(e) Horses treated with Shock Wave Therapy shall be placed on the Veterinarians' List for 30 days; and

(f) If before, during, or after the workout for removal from the Veterinarians' List, the Horse is deemed to be unsound or to have Bled, the stay on the Veterinarians' List shall be extended an additional 14 days, and further diagnostic testing may be required as determined by the Regulatory Veterinarian.

2242. Removal of Horses From the Veterinarians' List

Regulatory Veterinarians may remove Horses from the Veterinarians' List in accordance with Rule 2242 and shall document such removal to the Authority.

(a) A Horse placed on the Veterinarians' List as unsound or suffering from Epistaxis may be removed from the Veterinarians' List upon satisfaction of paragraphs (1) through (3) below.

(1) A trainer must apply to the Regulatory Veterinarian for permission to work the Horse for removal from Veterinarians' List. Upon receiving such approval, the Trainer and Attending Veterinarian must observe the Horse jog and submit to the Regulatory Veterinarian a co-signed statement that the Horse is fit to perform a Workout.

(2) The Horse must perform a Workout under the supervision of the Regulatory Veterinarian and demonstrate to the satisfaction of the Regulatory Veterinarian that the Horse is sound to race.

(3) The Regulatory Veterinarian determines there is no evidence or signs of Epistaxis, physical distress, medical compromise, unsoundness, or lameness within1 hour after the Workout conducted pursuant to paragraph (a)(2) above.

(b) A Horse placed on the Veterinarians' List as physically distressed or medically compromised may be removed from the Veterinarians' List provided sound health has been declared by the Attending Veterinarian or demonstrated to the Regulatory Veterinarian and documented to the Authority.

(c) In addition to the requirements set forth herein and any requirements of the Protocol, if a Horse is placed on the Veterinarians' List for a positive test or overage of a primary substance invoking a mandatory stand down time, a positive Out-of-Competition test, or any other veterinary administrative withdrawal, the Horse shall be prohibited from entering a Race and may be released from the Veterinarians' List only after also undergoing a post-Workout inspection by the Regulatory Veterinarian.

2250. Racehorse Treatment History and Records

2251. Veterinary Reports

(a) All Veterinarians shall provide treatment records pursuant to Rule Series 3000. In addition to the uses set forth therein, these records may be used by Regulatory Veterinarians in the performance of their duties at the racetrack, for transfer of 60 day medical records to the new trainer of a claimed Horse, and for purposes of research to enhance the safety and welfare of racehorses.

(b) In addition to the information required to be submitted by Veterinarians pursuant to Rule Series 3000, every Veterinarian who examines or treats a Covered Horse shall, within 24 hours of such examination or treatment, submit the following information in an electronic format designated by the Authority:

(1) The identity of the Horse treated;

(2) the name of the Trainer of the Horse;

(3) the name of the Veterinarian;

(4) contact information for the Veterinarian (phone, email address);

(5) any information concerning the presence of unsoundness and responses to diagnostic tests;

(6) diagnosis;

(7) condition treated;

(8) any medication, drug, substance, or procedure administered or prescribed, including date and time of administration, dose, route of administration (including structure treated if local administration), frequency, and duration (where applicable) of treatment;

(9) any non-surgical procedure performed (including but not limited to diagnostic tests, imaging, and shockwave treatment) including the structures examined/treated and the date and time of the procedure;

(10) any surgical procedure performed including the date and time of the procedure; and

(11) any other information necessary to maintain and improve the health and welfare of the Horse.

2252. Responsible Persons' Records

(a) In addition to the information required to be submitted by Responsible Persons under Rule Series 3000, a Responsible Person is responsible for maintaining a record of medical, therapeutic, and surgical treatments and procedures for every Covered Horse in his or her control.

(b) For purposes of this Rule, the term treatment:

(1) Means the administration of any medication or substance containing a medication to a Horse by a Responsible Person or his or her designee;

(2) includes the administration of medications that are prescribed by a Veterinarian but administered by the Responsible Person or his or her designee, or medications prescribed or administered by a Veterinarian not licensed by the State Racing Commission; and

(3) specifically excludes medications or procedures directly administered by a Veterinarian licensed by the State Racing Commission or that Veterinarian's employees.

(c) Records must include the information outlined in paragraphs (1) and (2) below.

(1) For medical treatments:

(i) Name of the Horse (or, if unnamed, the registered name of the dam and year of foaling);

(ii) name of Trainer;

(iii) generic name of the drug, or brand name if a non-generic drug is used;

(iv) name of the prescribing Veterinarian;

(v) date of the treatment;

(vi) route of administration;

(vii) dosage administered;

(viii) approximate time (to the nearest hour) of each treatment; and

(ix) full name and contact information of the individual who administered the treatment.

(2) For medical procedures, including, but not limited to, physiotherapy, acupuncture, chiropractic, and surgeries:

(i) Name of the Horse, or, if unnamed, the registered name of the dam and year of foaling;

(ii) name of Trainer;

(iii) diagnosis and condition being treated;

(iv) name of procedure or surgery;

(v) date of the procedure;

(vi) first and last name of the individual who administered or performed the procedure; and

(vii) any other information necessary to maintain and improve the health and welfare of the Horse.

(d) In addition to the uses of records set forth in the Rules Series 3000, records may be used by Regulatory Veterinarians in the performance of their duties at the Racetrack, for transfer of 60 day medical records to the new Owner of a claimed Horse, and for purposes of research to enhance the safety and welfare of racehorses. Records may also be accessed by the State Racing Commission or the stewards.

2253. Records for Horses Shipping to the Racetrack

(a) If a Horse is not stabled at a facility under the Authority's jurisdiction for the full 30 days prior to a Race or Workout for purposes of removal from the Veterinarians' List, the Responsible Person shall obtain and maintain the following information for the previous 30 days:

(1) Name of the Horse or, if unnamed, the registered name of the dam and year of foaling;

(2) generic name of the drug, or brand name of the drug if a non-generic drug is used;

(3) date and duration of the treatment;

(4) route of administration;

(5) dosage administered;

(6) surgical procedures;

(7) non-surgical therapies and procedures; and

(8) any other information necessary to maintain and improve the health and welfare of the Horse.

(b) If a Horse is not stabled at a facility under the Authority's jurisdiction for 60 days prior to a Race or Workout for purposes of removal from the Veterinarians' List, the Responsible Person shall obtain and maintain the following information:

(1) The last 30 days of exercise activity at the facility;

(2) the last 30 days of treatments and procedures at the facility; and

(3) any other information necessary to maintain and improve the health and welfare of the Horse.

2260. Claiming Races

2261. Transfer of Claimed Horse Records

(a) Entry of Horses subject to being claimed in a Claiming Race implies Owner (Trainer as the agent of the Owner) consent for transfer of all Trainer and veterinary examination and treatment records for the last 60 days to the new Trainer of the claimed Horse.

(b) If a Horse is successfully claimed by a new Trainer, the previous Trainer must transfer Trainer records and authorize transfer of veterinary records to the new Trainer within 3 days of transfer of the Horse to the new Trainer.

2262. Void Claim

(a) Title to a Horse which is claimed shall be vested in the successful claimant from the time the field has been dispatched from the starting gate and the Horse becomes a starter.

(b) All claimed Horses shall go to the test barn for observation by the Regulatory Veterinarian.

(c) The claim shall be voided, and ownership of the Horse retained by the original Owner if:

(1) The Horse dies on the racing track;

(2) the Horse is euthanized before leaving the racing track;

(3) the Horse is vanned off of the racing track by discretion of the Regulatory Veterinarian;

(4) the Regulatory Veterinarian determines within 1 hour of the race that the Horse will be placed on the Veterinarians' List as Bled, physically distressed, medically compromised, unsound, or lame before the Horse is released to the successful claimant; or

(5) the Horse has a positive test for a Prohibited Substance.

(d) The claim shall not be voided if, prior to the Race in which the Horse is claimed, the claimant elects to claim the Horse regardless of whether the Regulatory Veterinarian determines the Horse will be placed on the Veterinarians' List as Bled or unsound or the Horse tests positive for a Prohibited Substance.

2262. Waiver Claiming Option

At time of entry into a Claiming Race an Owner or Trainer may opt to declare a Horse ineligible to be claimed provided:

(a) The Horse has not started in 120 days;

(b) the Horse's last start must have been for a claiming price; and

(c) the Horse is entered for a claiming price equal or greater than the price it last started for.

2270. Prohibited Practices and Requirements for Safety and Health of Horses

2271. Prohibited Practices

The following are prohibited practices:

(a) Use of physical or veterinary procedures to mask the effects or signs of injury so as to allow training or racing to the detriment of the Horse's health and welfare.

(b) Use of extracorporeal shock wave therapy in a manner that may desensitize any limb structures during racing or training.

(c) Surgical or chemical neurectomy to cause desensitization of musculoskeletal structures associated with the limbs.

(d) Thermocautery including but not limited to pin firing and freeze firing, or application of any substance to cause vesiculation or blistering of the skin, or a counter-irritant effect.

(e) Use of a device to deliver an electrical shock to the Horse including but not limited to cattle prods and batteries.

(f) Use of electrical medical therapeutic devices including magnetic wave therapy, laser, electro-magnetic blankets, boots, electro-shock, or any other electrical devices that may produce an analgesic effect within 48 hours of a training activity or of the start of the published post time for which a Horse is scheduled to race.

2272. Shock Wave Therapy

(a) The use of Shock Wave Therapy shall be disclosed to the Regulatory Veterinarian no less than 48 hours prior to use and shall not be permitted unless the following conditions are met:

(1) Any Shock Wave Therapy may only be performed with machines that are:

(i) Registered and approved for use by the State Racing Commission; and

(ii) used at a previously disclosed location that is approved by the State Racing Commission.

(2) The use of Shock Wave Therapy shall be limited to licensed Veterinarians and must be reported to the Regulatory Veterinarian within 48 hours of treatment to the Authority.

(3) Any treated Horse shall be placed on the Veterinarians' List and shall not be permitted to Race or breeze for 30 days following treatment.

(b) The Veterinarian and Trainer shall be suspended from the Racetrack for a period of 5 days if Shock Wave Therapy

has not been reported within 48 hours of any treatment or procedure administered to a Covered Horse. For each subsequent omission of reporting, an additional 5 days suspension shall be added. If there are 3 violations in a calendar year, the Veterinarian and Trainer shall be suspended for 6 months in the subsequent calendar year.

2273. Other Devices

No electrical or mechanical device or other expedient designed to increase or retard the speed of Covered Horse, other than the riding crop permitted under these regulations, shall be possessed by anyone, or applied by anyone, to a Covered Horse at any time on Racetrack grounds or during a Workout.

2274. Other Device Penalties

Penalties for violations of Rule 2273 shall be as follows:

(a) The penalty for a first offense shall be loss of eligibility to obtain a racing license in all racing jurisdictions for 10 years.

(b) For any subsequent violation, the penalty shall be loss of eligibility to obtain a racing license in all racing jurisdictions for the life of the Covered Person.

2275. Communication Devices

The use of a hand-held communication device by a rider is prohibited while the rider is on the racing track.

2276. Horseshoes

(a) Except for full rims 2 millimeters or less from the ground surface of the Horseshoe, traction devices are prohibited on forelimb and hindlimb Horseshoes during racing and training on dirt or synthetic racing tracks.

(b) Traction devices are prohibited on forelimb and hindlimb Horseshoes during training and racing on the turf.

(c) Traction devices include but are not limited to rims, toe grabs, bends, jar calks and stickers.

2280. Use of Riding Crop

(a) A Jockey or exercise rider who uses a crop during a Race or Workout shall do so only in a professional manner consistent with maintaining focus and concentration of the Horse for safety of Horses and riders, or for encouragement to achieve optimal performance.

(b) A rider may:

(1) Use the crop on the hindquarters to activate and focus the Horse a maximum of 6 times during a race. The 6 permitted uses shall be in increments of 2 or fewer strikes. The rider must allow at least 2 strides for the Horse to respond before using the crop again.

(2) Tap the Horse on the shoulder with the crop while both hands are holding on to the reins and both hands are touching the neck of the Horse.

(3) Show or wave the crop to the Horse without physically contacting the Horse.

(4) Use the crop to preserve the safety of Horses and riders.

(c) A rider may not:

(1) Raise the crop with the rider's wrist above the rider's helmet when using the crop;

(2) Injure the Horse with the crop or leave any physical marks, such as welts, bruises, or lacerations;

(3) Use the crop on any part of the Horse's body other than the shoulders or hindquarters;

(4) Use the crop during the post parade or after the finish of the race other than to avoid a dangerous situation or preserve the safety of Horses and riders;

(5) Use the crop if the Horse has obtained its maximum placing;

(6) Use the crop persistently even though the Horse is showing no response;

(7) Use a crop on a 2-year-old Horse in races before April 1 of each year other than to avoid a dangerous situation or preserve the safety of Horses and riders; or

(8) Strike another Horse or person with the crop.

(d) In any Race in which a Jockey will ride without a crop, that fact shall be declared at entry, included in the official program, and an announcement of that fact shall be made over the public address system.

2281. Riding Crop Specifications

(a) Riding crops are subject to inspection by the Safety Officer, stewards, and the clerk of the scales.

(b) All riding crops must be soft-padded.

(c) Riding crops shall have a shaft and a smooth foam cylinder and must conform to the following dimensions and construction:

(1) The maximum allowable weight shall be 8 ounces;

(2) The maximum allowable length, including the smooth foam cylinder attachment, shall be 30 inches;

(3) The minimum diameter of the shaft shall be three-eighths of one inch; and

(4) The shaft, beyond the grip, must be smooth, with no protrusions or raised surface, and covered by shock absorbing material that gives a compression factor of at least one millimeter throughout its circumference.

(5) There shall be no binding within 7 inches of the end of the shaft.

(6) The smooth foam cylinder is the only allowable attachment to the shaft and must meet the following specifications:

(i) Shall have no reinforcements;

(ii) Shall have a maximum length beyond the shaft of one inch;

(iii) Shall have a minimum diameter of 0.8 inches and a maximum width of 1.6 inches;

(iv) There shall be no other reinforcements or additions beyond the end of the shaft;

(v) Shall be made of shock absorbing material with a compression factor of at least 5 millimeters throughout its circumference;

(vi) Shall be made of a waterproof, ultraviolet, and chemical resistant foam material that is durable and preserves its shock absorption in use under all conditions; and

(vii) Shall be replaced after reasonable wear and tear is visibly evident.

(7) Riding crops shall not be altered and shall have an appropriate label or marking designating that the riding crop meets the required standards as established by the Authority.

2282. Riding Crop Violations and Penalties

(a) Violations of Rule 2280 shall be categorized as follows, with the exception that use of the crop for the safety of Horse and rider shall not count toward the total crop uses:

(1) Class 3 Violation—1 to 3 strikes over the limit.

(2) Class 2 Violation—4 to 9 strikes over the limit.

(3) Class 1 Violation—10 or more strikes over the limit.

(b) Unless the stewards determine the merits of an individual case warrant consideration of an aggravating or mitigating factor, the penalties for violations are as follows:

(1) Class 3 Violation—

(i) $250 or 10% of Jockey's portion of the purse, whichever is greater;

(ii) Minimum 1-day suspension for the Jockey; and

(iii) 3 points;

(2) Class 2 Violation—

(i) $500 or 20% of Jockey's portion of the purse, whichever is greater;

(ii) Horse disqualified from purse earnings,

(iii) Minimum 3-day suspension for the Jockey; and

(iv) 5 points;

(3) Class 1 Violation—

(i) $750 fine or 30% of Jockey's portion of the purse, whichever is greater,

(ii) Horse disqualified from purse earnings,

(iii) Minimum 5-day suspension for the Jockey;

(iv) 10 points.

2283. Multiple Violations

(a) Stewards shall submit violations of Rule 2282 to the Authority to identify when multiple violations warrant additional suspensions consistent with the following schedule:

(1) 11–15 points: 7 days.

(2) 16–20 points: 15 days.

(3) 21 or more points: 30 days.

(b) Points assigned under Rule 2282 shall expire according to the following schedule:

(1) Class 3 Violation: 6 months.

(2) Class 2 Violation: 9 months.

(3) Class 1 Violation: 1 year.

(c) For purposes of paragraph (b), points are expunged from the date of final adjudication of the violation and not from the date of the violation. Mandatory suspensions are based on points accumulated for multiple violations and do not apply to single violations.

2290. Requirements for Safety and Health of Jockeys

2291. Jockey Eligibility

(a) A Jockey shall pass a physical examination given within the previous 12 months by a licensed physician affirming the Jockey's fitness to participate as a Jockey, as well as a baseline Concussion test using a current Concussion testing protocol. The results of the physical examination and the baseline Concussion test shall be submitted to the State Racing Commission and the Authority.

(b) The stewards may require that any Jockey be reexamined and may refuse to allow any Jockey to ride in a race or Workout pending completion of such examination.

2292. Jockey and Exercise Rider Medical History Information

(a) At all times while mounted on a Horse at a Racetrack, a Jockey or exercise rider shall securely attach to his or her safety vest one or more medical information cards describing his or her medical history and any conditions pertinent to emergent care, including a listing of any previous injuries, drug allergies and current medications.

(b) The stewards shall confirm compliance during their safety vest inspections at the beginning of the season and with random inspections throughout the Race Meet.

(c) The stewards may, in their discretion, take disciplinary action against, suspend, make ineligible to race, or fine any Jockey or exercise rider found in violation of Rule 2292.

2293. Equipment

(a) Helmets.

(1) Any person mounted on a Horse or stable pony anywhere on racetrack grounds shall always wear a properly secured safety helmet.

(2) All starting gate personnel shall always wear a properly secured safety helmet while performing their duties or handling a Horse.

(3) The safety helmet may not be altered in any manner and the product marking shall not be removed or defaced.

(4) The stewards, or their designees, shall inspect safety helmets at the beginning of a Race Meet and randomly throughout the Race Meet.

(5) The Clerk of Scales shall report to the stewards any variances of safety helmets seen during the course of their work.

(6) The helmet must comply with one of the following minimum safety standards or later revisions:

(i) American Society for Testing and Materials (ASTM 1163);

(ii) European Standards (EN–1384 or PAS–015 or VG1);

(iii) Australian/New Zealand Standards (AS/NZ 3838 or ARB HS 2012); or

(iv) Snell Equestrian Standard 2001.

(b) Vests.

(1) Any person mounted on a Horse or stable pony on the racetrack grounds must wear a properly secured safety vest at all times.

(2) All starting gate personnel must wear a properly secured safety vest at all times while performing their duties or handling a Horse.

(3) The safety vest may not be altered in any manner and the product marking shall not be removed or defaced.

(4) The stewards shall inspect safety vests at the beginning of a Race Meet and randomly throughout the Race Meet.

(5) The clerk of scales shall report to the stewards any variances of safety vests seen during their course of work.

(6) The safety vest must comply with one of the following minimum standards, as the same may be from time to time amended or revised:

(i) British Equestrian Trade Association (BETA):2000 Level 1;

(ii) iEuro Norm (EN) 13158:2000 Level 1;

(iii) American Society for Testing and Materials (ASTM) F1781–08 or F1937;

(iv) Shoe and Allied Trade Research Association (SATRA) Jockey Vest Document M6–3; or

(v) Australian Racing Board (ARB) Standard 1.1998.

Appendix—Supporting Documentation Submitted by HISA

The Authority submitted a variety of materials to reflect existing standards, scientific data, studies, and analysis utilized in the development of the proposed rules, which are available for public inspection at *https://www.regulations.gov* under docket number FTC–2021–0076. These materials are referred to in the Authority's filing as exhibits, a complete list of which appears below:

Exhibit 1—National Thoroughbred Racing Association Safety & Integrity Alliance Code of Standards (2021).

Exhibit 2—Association of Racing Commissioners International, Model Rules of Racing, Version 10.1 (2021), *https://www.arci.com/wp-content/uploads/2021/12/MODELRULESMASTERVERSION10.11129.pdf.*

Exhibit 3—A comparison of the substantive terms of the proposed rule with safety standards and provisions of the NTRA Code of Standards and the specific ARCI Rules.

Exhibit 4—International Federation of Horseracing Authority, International Agreement on Breeding, Racing and Wagering.

Exhibit 8—Mid-Atlantic Strategic Plan to Reduce Equine Fatalities Goal l: Develop regional safety best practices.

Exhibit 9—Mid-Atlantic Strategic Plan to Reduce Equine Fatalities—Best Practices Mortality Review Board.

Exhibit 10—California Code of Regulations Article 15; Veterinary Practices 1846.5; Postmortem Examination (a)–(h).

Exhibit 11—Jockeys' Guild, Inc. and the NTRA Safety & Integrity Alliance Medical Director Committee, Medical Care Recommendations.

Exhibit 12—AAEP Healthy Horse Protocol: Biosecurity Guidelines for Racetrack Entry and Stabling (2020).

Exhibit 13—AAEP General Biosecurity Guidelines.

Exhibit 14—AAEP Clinical Guidelines for Veterinarians Practicing in a Pari-Mutuel Environment—Infectious Disease Control.

Exhibit 15—Walsh KM, Cooper MA, Holle R, Rakov VA, Roeder WP, Ryan M. ''Lightning Safety for Athletics and Recreation.'' Journal of Athletic Training (2013): 258–70.

Exhibit 16—American Association of Equine Practitioners, Thoroughbred Race Day Injury Management Guidelines.

Exhibit 17—Equine Disease Communication Center website.

Exhibit 18—National Thoroughbred Racing Association Safety & Integrity Alliance Code of Standards: Surfaces 2020.

Exhibit 19—Racing Surfaces Testing Laboratory website.

Exhibit 20—AAEP Guidelines, Necropsies of Racehorses, General Guidelines, Revised by AAEP Racing Committee 2020.

Exhibit 21—NYCRR Title 9, Executive Subtitle T New York State Gaming Commission Chapter 1 Division of Horse Racing and Pari-mutuel Wagering, Subchapter A Thoroughbred Racing, Article 1 Rules of Racing, Part 4007 Horses.

Exhibit 22—Thoroughbred Horseman's Association, Continuing Education for Trainers and Assistant Trainers.

Exhibit 23—Centers for Disease Control, Heads Up—Brain Injury Basics—Returning to Sports and Activities.

Exhibit 24—National Athletic Trainers' Association Position Statement: Management of Sports Concussion.

Exhibit 25—MedStar Sports Medicine Concussion Protocol for Jockeys and Horsemen.

Exhibit 26—MedStar Sports Medicine—Concussion Protocol video.

Exhibit 27—The Jockey Club Thoroughbred Safety Committee Recommendation, August 12, 2012 (revised August 5, 2021).

Exhibit 28—Kane AJ, Stover SM, Gardner IA, et al. Horseshoe characteristics as possible risk factor for fatal musculoskeletal injury of Thoroughbred racehorses. American Journal of Veterinary Research, 1996, Vol. 57, No. 8, Pages 1147–52.

Exhibit 29—Casner B. 2010 Jockey Club Welfare & Safety Committee Presentation—Welfare and Safety of the Racehorse Summit.

Exhibit 30—Harvey AM, Williams SB, Singer ER. The effect of lateral heel studs on the kinematics of the equine digit while cantering on grass. Veterinary Journal 2012 May;192(2):217–21. doi: 10.1016/j.tvjl.2011.06.003. Epub 2011 Jul 12. PMID: 21752677.

Exhibit 31—Hill AE, Gardner IA, Carpenter TE, Stover SM. Effects of injury to the suspensory apparatus, exercise, and horseshoe characteristics on the risk of lateral condylar fracture and suspensory apparatus failure in forelimbs of Thoroughbred racehorses. American Journal Veterinary Research, 2004, 65 (11), 1508–17.

Exhibit 32—Hill AE, Stover SM, Gardner IA, et al. Risk factors for and outcomes of noncatastrophic suspensory injury in Thoroughbred racehorses. Journal American Veterinary Medical Association. 2001, Vol. 218, 1136–44.

Exhibit 33—Hernandez JA, Scollay MC, Hawkins DL, et al. Evaluation of horseshoe characteristics and high-speed exercise history as possible risk factors for catastrophic musculoskeletal injury in Thoroughbred racehorses. American Journal Veterinary Research 2005; 66:1314–1320.

Exhibit 34—Anthenill LA, Stover SM, Garner IA, Hill AE. Risk Factors for proximal sesamoid bone fractures associated with exercise history and horseshoe characteristics in Thoroughbred racehorses. American Journal Veterinary Research, 2007, 68 (7), 760–71.

Exhibit 35—Kentucky Horse Racing Commission Administrative Regulations—810 KAR 4:010. Horses—Section 11 Equipment.

Exhibit 36—IFHA Use of the Whip, ''IFHA Principles of Good Practice for the use of the Whip in Horseracing.''

Exhibit 37—Schambourg nociceptive thresholds in endurance horses, Vet Rec 2019.

Exhibit 38—The Use of Whips in Thoroughbred Racing in Australia, RSPCA Information Paper—November 2020.

Exhibit 39—Thompson—Is Whip Use Important to Thoroughbred Racing Integrity? What Stewards' Reports Reveal about Fairness to Punters, Jockeys and Horses—Animals, 1985.

Exhibit 40—Toma—Assessing Forces Exerted on Horses Using Varying Riding Crop—Journal of Equine Veterinary Science, 2021.

Exhibit 41—Tong—A Comparative Neuro-Histological Assessment of Gluteal Skin.

Exhibit 42—Ueda Y, Yoshia K, Oikawa M. Analysis of race accident conditions through use of patrol video. J Equine Vet Sci 1993;13:707–710.

Exhibit 43—Deuel—Effects of Urging by the Rider on Gallop Stride Characteristics of Quarter Horses—Equine Nutrition and Physiology Society—1988 Issue.

Exhibit 44—McGreevy—Whip Use by Jockeys in a Sample of Australian Thoroughbred Races—An Observational Study—PLOS ONE 2012.

Exhibit 45—Pinchbeck—Whip use and race progress are associated with horse falls in hurdle and steeplechase racing in the UK—Equine Veterinary Journal, 2004.

Exhibit 46—Mills and Higgins—Investigation of the Potential of Whips to Injure Horses—1996.

Exhibit 47—Jones—A Critical Analysis of the British Horseracing Authority's Review of the Use of the Whip in Horseracing—Animals 2015.

Exhibit 48—Luna—Validation of mechanical, electrical and thermal nociceptive stimulation methods in horses—Equine Veterinary Journal 2015.

Exhibit 49—McGreevy—A note on the force of whip impacts delivered by jockeys using forehand and backhand strikes—Journal of Veterinary Behavior 2013.

Exhibit 50—Evans—An Investigation of Racing Performance and Whip Use by Jockeys in Thoroughbred Races—PLOS ONE 2011.

Exhibit 51—Graham—Changing Human-Animal Relationships in Sport: An Analysis of the UK and Australian Horse Racing Whips Debates, Animals, 2016.

Exhibit 52—Haussler—Mechanical nociceptive thresholds in the axial skeleton of horses, Equine Veterinary Journal, 2006.

Exhibit 53—ARCI Crop Rule Penalties—ARCI–010–035 Running of the Race—(Proposed Rule Text).

Exhibit 54—The Jockey Club Thoroughbred Safety Committee Recommendation, August 14, 2016 (modified 8/11/19).

Exhibit 55—California Proposed Crop Equipment Rule—1685. Equipment Requirement.

Exhibit 56—New Jersey Rule 13:70–11.12.

Exhibit 57—Gulfstream Park Crop Rule.

Exhibit 58—British Horseracing Authority Rules of Racing 1 October 2021 Version 2021.4.1, 4–Whip Rule (F)45.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2021–28513 Filed 1–4–22; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PAR 18–812, NIOSH Member Conflict Review.

Date: February 23, 2022.

Time: 1:00 p.m.–4:00 p.m., EST.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, CDC, 1095 Willowdale Road, Morgantown, West Virginia 26506, Telephone: (304) 285–5951, Email: *MGoldcamp@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–28521 Filed 1–4–22; 8:45 am]

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Exhibit

E

HORSERACING INTEGRITY AND SAFETY AUTHORITY

Horseracing Integrity and Safety Authority Announces Proposed Implementation Date for Anti-Doping and Medication Control Program

December 7, 2021 (Lexington, KY) - Today, the Horseracing Integrity and Safety Authority (HISA) announced the proposed implementation date of the Anti-Doping and Medication Control (ADMC) program. Under the proposed structure, out-of-competition testing would be administered, under HISA's jurisdiction, beginning with the program's effective date in July 2022. Race-day testing would remain under the jurisdiction of state regulators until the beginning of 2023 at which point this would transition to HISA's jurisdiction.

The proposed structure was announced by HISA Board Chair Charles Scheeler at the Global Symposium on Racing, hosted by the University of Arizona. Scheeler addressed the industry event along with Adolpho Birch, Chair of the Anti-Doping and Medication Control standing committee, and Susan Stover, Chair of the Racetrack Safety standing committee. The event marked the first time HISA officials addressed public audiences on the proposed rules and progress to date.

HISA and USADA developed the Anti-Doping and Medication Control approach in response to extensive feedback from regulators and other industry stakeholders. Specifically, the phased approach would allow:

- A less disruptive transition to race-day testing from the middle of the racing season to the beginning of a new season
- State Racing Commissions to synchronize budget cycles more easily
- Laboratories more time to adapt to new standards
- Greater opportunities for additional education on the new procedures and protocols for covered persons
- More thorough testing and implementation of needed new technology solutions

"We have heard consistent feedback from stakeholders across the industry about the need for a phased implementation timeline for the Anti-Doping and Medication Control program. We agree with the feedback and believe the proposed phased approach will create a more efficient and effective program," said HISA Board Chair Charles Scheeler. "The timeline will give all parties involved an opportunity to adapt to the new rules and will ultimately lead to greater confidence in the system, all while still ensuring continuity in the testing of equine athletes."

As announced yesterday, the Racetrack Safety proposed rules have been submitted to the FTC for review, public comment and approval with an effective date of July 1, 2022. Draft Anti-Doping and Medication Control rules will be submitted later in December, before the new year.

Please visit hisaus.org and follow the Authority on Twitter and Facebook to keep up with the latest developments.

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HORSERACING INTEGRITY AND SAFETY AUTHORITY

MEDIA CONTACT
MacKenzie Smith
202-262-2650
mackenzie.smith@fgh.com

Exhibit

F

HISA REGULATIONS

Definitions

AAEP: American Association of Equine Practitioners

Act: The Horseracing Integrity and Safety Act of 2020.

Additional Last Name: mothers maiden name is used on legal documents

Administration: Providing, supplying, supervising, facilitating, or otherwise participating in the Use or Attempted Use in a Covered Horse by a Covered Person of a Prohibited Substance or Prohibited Method.

Adverse Analytical Finding: A report from a Laboratory that, consistent with the Laboratory Standards establishes in a Sample the presence of a Prohibited Substance or its Metabolites or Markers or evidence of the Use of a Prohibited Method

Adverse Passport Finding: A report identified as an Adverse Passport Finding as described in the applicable Policies.

Agency: The United-States Anti-Doping Agency or any entity contracted by the Authority to fulfill the responsibilities under the Protocol and the Act.

Aggravating Circumstances: Circumstances involving, or actions by, a Covered Person which may justify the imposition of a period of Ineligibility greater than otherwise imposed. Such circumstances and actions shall include, but are not limited to: administration that is detrimental to the health and welfare of the horse or is designed to deceive the betting public; the Covered Person Possessing, Administering, or Trafficking multiple Prohibited Substances or Prohibited Methods; the Covered Person Possessing, Administering, or Trafficking a Prohibited Substance or Prohibited Method on multiple occasions or committing multiple other anti-doping or medication control rule violations; a Covered Horse or Covered Person would be likely to enjoy the performance-enhancing effects or consequences of the performance-enhancing effects of the anti-doping or medication control rule violation(s) beyond the otherwise applicable period of Ineligibility; the Covered Person engaged in deceptive or obstructive conduct to avoid the detection or adjudication of an anti-doping or medication control rule violation; or the Covered Person engaged in Tampering during Results Management. For the avoidance of doubt, the examples of circumstances and conduct described herein are not exclusive and other similar circumstances or conduct may also justify Aggravating Circumstances and the imposition of a longer period of Ineligibility.

Aliquot: A portion of the Sample of biological fluid (e.g., urine, blood) obtained from the Covered Horse used in the analytical process.

Analyte: Also known as or referred to as a substance, compound or measurand, which is analyzed and/or determined in a biological matrix using an Analytical Testing Procedure performed under controlled analytical and laboratory conditions. For anti-doping and medication control purposes, an Analyte may be a Prohibited Substance, a Metabolite of a Prohibited Substance, or a Marker of the Use of a Prohibited Substance or Prohibited Method.

Analytical Method: Analytical Testing Procedure, Test Method.

Analytical Testing Procedure: A Fit-for-Purpose procedure, as demonstrated through method validation, and used to detect, identify and/or quantify Analytes in a Sample for Doping Control purposes in accordance with the Laboratory Standards and relevant Technical Document(s), Technical Letter(s), or Laboratory Guidelines. An Analytical Testing Procedure is also referred to or known as an Analytical Method or Test Method.

Analytical Testing Restriction (ATR): Restriction on a Laboratory's application of specified Analytical Testing Procedure(s) or the analysis of a particular class(es) of Prohibited Substances or Prohibited Methods to Samples, as determined by the Agency.

Analytical Testing: The parts of the Doping Control process performed at the Laboratory, which include Sample handling, analysis and reporting of results.

Anti-Doping Stewards Panel: Impartial stewards or former stewards appointed by the Agency to hear Minor Infractions cases on a rotating basis pursuant to Article 8.2 (a).

Arbitration Procedures: The arbitration procedures for the Equine Anti-Doping and Medication Control Protocol developed pursuant to the Act and the Protocol, which are Standards.

Assistant Trainer: A Person engaged in the training of Covered Horses under the direct supervision of a Trainer

Association Veterinarian: A Veterinarian employed by an Association.

Association: Shall have the same definition as Racetrack

Attempt: Purposely engaging in conduct that constitutes a substantial step in a course of conduct planned to culminate in the commission of an anti-doping or medication control rule violation. Provided, however, there shall be no anti-doping or medication control rule violation based solely on an Attempt to commit a violation if the Person renounces the Attempt prior to it being discovered by a third party not involved in the Attempt.

Attending Veterinarian: A Veterinarian hired by the Trainer and/or Owner

Atypical Finding: A report from a Laboratory which requires further investigation as provided by the Laboratory Standards or related Technical Documents prior to the determination of an Adverse Analytical Finding.

Atypical Passport Finding: A report described as an Atypical Passport Finding as described in the Policies.

Authority: The Horseracing Integrity and Safety Authority.

Batch: A set of Samples processed as a group.

Bias: Deviation of a measured result from the expected or reference value when using the complete measurement procedure.

Billing Standards: The Standards governing compensation for arbitrators and stewards under the Arbitration Procedures.

Bled: the observation of blood from one or both nostrils as a result of exercise induced pulmonary hemorrhage

Blood Collection Officer (BCO): An official who is a veterinarian or a veterinary technician and has been authorized by the Agency to collect a blood Sample from a Covered Horse.

Breeder: A Person who is in the business of breeding Covered Horses

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

Chain of Custody: The sequence of individuals or organizations who have responsibility for the custody of a Sample.

Chaperone: An official who is suitably trained and authorized by the Agency to carry out the responsibilities given to Chaperones in the Testing and Investigations Standards and/or by the DCO.

Claiming Race: A race in which a horse after leaving the starting gate may be claimed (purchased for a designated amount) in accordance with State Racing Commission rules

Commission: The Federal Trade Commission

Concussion: An injury to the brain that results in temporary loss of normal brain function

Confirmation Procedure (CP): An Analytical Testing Procedure that has the purpose of confirming the presence and/or, when applicable, confirming the concentration/ratio/score and/or establishing the origin (exogenous or endogenous) of one or more specific Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method in a Sample.

Consequences of Anti-Doping and Medication Control Rule Violations (“Consequences”): Covered Person’s violation of an anti-doping rule may result in one or more of the following: (a) Disqualification means the results in a particular Race are invalidated, with all resulting Consequences including forfeiture of any purses, points, and prizes; (b) Ineligibility means the Covered Horse or Covered Person is barred on account of an anti-doping or medication control rule violation for a specified period of time from participating in any Covered Horserace or activity involving Covered Horses or Racetracks as set forth in Article 10.12; (c) Provisional Suspension means the Covered Horse or Covered Person is barred temporarily from participating in any Covered Horserace or activity involving Covered Horses or Racetracks as set forth in Article 10.12 (Status During Ineligibility or Provisional Suspension) prior to the final decision pursuant to Article 8; (d) Fine means a financial sanction imposed for an anti-doping or medication control rule violation or to recover costs associated with an anti-doping or medication control rule violation that shall be paid to the Authority; and (e) Public Disclosure means the dissemination or distribution of information to the general public or Persons beyond those Persons entitled to earlier notification in accordance with the Protocol.

Contaminated Product: A product (other than normal feed or water) that contains a Prohibited Substance that is not disclosed on the product label or in information available in a reasonable internet search.

Cooperate: Failure by the Responsible Person to properly or truthfully file or timely update designations as to the identity of the Responsible Person for a Covered Horse or properly maintain Treatment records for a Covered Horse as described in Article 16 of the Protocol. Failure by the Owner to properly or truthfully file or timely update ownership or property interests in a Covered Horse or the identity of the managing Owner. And with respect to any matter under the Agency’s authority, a Covered Person’s failure to respond promptly, truthfully, and completely to written and oral inquiries from the Agency or adjudication body as well as to subpoenas issued by the Agency or Authority. At the request of the

Agency, a Covered Person's failure to (a) make available any facility, office, stall, equipment, feed, medicine, etc.; (b) submit to under oath transcribed interviews; (c) provide immediate access to records related to any Covered Horse; and (d) provide immediate access to electronically stored data, including emails, computers, and mobile phones and devices without alteration.

Corrective Action Report (CAR): A report describing the Root Cause Analysis investigation of a detected nonconformity and the corrective actions implemented to rectify it. If appropriate, it shall also describe the improvements adopted to minimize the risk of recurrence of the nonconformity.

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

Covered Horse: Any thoroughbred horse, or any other horse made subject to this Protocol by election of the applicable State Racing Commission or the breed governing organization for such horse beginning on the earlier of (1) the date of the horse's first timed and reported Workout at a Racetrack; (2) the date of the horse's first timed and reported workout at a Training Facility; (3) the date of the horse's entry in a Covered Horserace; or (4) the date of the horse's nomination for a Covered Horserace, and ending on the date on which the Agency receives written notice that the horse has been retired in accordance with the Protocol. A Covered Horse that has been fatally injured or dies prior to retirement remains subject to Agency jurisdiction, including Sample collection, after notification of retirement.

Covered Horserace: Any horserace event involving Covered Horses from the official opening of such event through the conclusion of all the Sample collection process for all Covered Horses in connection with the event.

covered person agreement from the regulations web site Lorem ipsum dolor sit amet, consectetur adipiscing elit, sed do eiusmod tempor incididunt ut labore et dolore magna aliqua. Sed felis eget velit aliquet sagittis id consectetur purus ut. Vestibulum mattis ullamcorper velit sed ullamcorper morbi tincidunt. Porttitor lacus luctus accumsan tortor posuere. Congue nisi vitae suscipit tellus mauris a diam maecenas sed. Sed viverra tellus in hac habitasse. Vitae elementum curabitur vitae nunc sed velit. Arcu cursus vitae congue mauris rhoncus aenean vel. Neque convallis a cras semper auctor neque vitae tempus quam. Malesuada fames ac turpis egestas integer eget. Malesuada proin libero nunc consequat interdum varius sit amet mattis. Lobortis feugiat vivamus at augue eget arcu. Eu tincidunt tortor aliquam nulla facilisi cras fermentum odio eu. Tellus in metus vulputate eu scelerisque. Ut pharetra sit amet aliquam id diam maecenas. Adipiscing at in tellus integer feugiat. Gravida rutrum quisque non tellus orci. Aliquet nec ullamcorper sit amet. Suscipit adipiscing bibendum est ultricies integer. In hendrerit gravida rutrum quisque.

Covered Persons: All Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, and Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such persons and other horse support personnel who are engaged in the care, training, or racing of Covered Horses.

Decision Limit: The value of the result for a Threshold Substance in a Sample, above which an Adverse Analytical Finding shall be reported, as defined in the Laboratory Standards

Disqualification: See Consequences of Anti-Doping and Medication Rule Violations above.

Doping Control Officer (DCO): An official who has been trained and authorized by the Agency to carry out the responsibilities given to DCOs in the Testing and Investigations Standards.

Doping Control: All steps and processes from test distribution planning through to ultimate disposition of any appeal and the enforcement of Consequences, including all steps and processes in between, including but not limited to, Testing, investigations, whereabouts, Sample collection and handling, Laboratory analysis, Results Management and investigations and proceedings relating to violations of Article 10.12 (Status During Ineligibility or Provisional Suspension).

Epistaxis: Blood from one or both nostrils as a result of exercise induced pulmonary hemorrhage

Equine Ambulance: A vehicle for the transport of an injured horse

Equine Biological Passport: The program and methods of gathering and collating data as described in the Testing and Investigations Standards and Laboratory Standards.

Equine Constituencies: Collectively, Owners, Breeders, Trainers, Racetracks, Veterinarians, State Racing Commissions, and Jockeys who are engaged in the care, training, or racing of Covered Horses.

Equine Passport Management Unit (EPMU): A unit composed of a person or persons that is responsible for the timely management of Equine Biological Passports on behalf of the Agency.

Expanded Measurement Uncertainty: The Expanded Measurement Uncertainty is calculated by multiplying the Coverage Factor (q.v.) by the Measurement Uncertainty (q.v.).

External Quality Assessment Scheme (EQAS): Program for quality assessment of Laboratory performance, which includes the periodical distribution of urine, blood or other Samples to Laboratories and probationary laboratories by the

Agency, to be analyzed for the presence or absence of Prohibited Substances and/or their Metabolite(s), or Marker(s) of Use of Prohibited Substances or Prohibited Methods. EQAS samples may be open (i.e., educational; in such cases the content may be indicated), blind or double-blind (in such cases the content is unknown to the Laboratories).

Failure to Comply: A term used to describe anti-doping rule violations under Articles 2.3 and/or 2.5 of the Protocol.

Farrier: a farrier licensed to be on the back side

Fault: Fault is any breach of duty or any lack of care appropriate to a particular situation. For a Fault reduction in connection with an Adverse Analytical Finding, the Covered Person must establish the source of an Adverse Analytical Finding. Factors to be taken into consideration in assessing a Covered Person's degree of Fault include, for example, the Covered Person's experience, special considerations such as impairment, the degree of risk that should have been perceived by the Covered Person and the level of care and investigation exercised by the Covered Person in relation to what should have been the perceived level of risk. With respect to supervision, factors to be taken into consideration are the degree to which the Covered Person vetted, monitored, and educated subordinates and created and maintained systems to ensure compliance with the anti-doping rules. In assessing the Covered Person's degree of Fault, the circumstances considered must be specific and relevant to explain the Covered Person's departure from the expected standard of behavior. Thus, for example, the fact that the Covered Person would lose the opportunity to earn large sums of money during a period of Ineligibility, or the fact that the Covered Person only has a short time left in a career, or the timing of the racing calendar, would not be relevant factors to be considered in reducing the period of Ineligibility under Article 10.6.

Fine: See Consequences of Anti-Doping and Medication Control Rule Violations above.

First Name: a persons legal first name aka given name

Fit(ness)-for-Purpose: Suitable for the intended purpose and in conformity with the ISO/IEC 17025 or ISO 15189, as applicable, ILAG-G7, the Laboratory Standards and relevant Technical Document(s) and Technical Letter(s).

Flexible Scope of ISO/IEC 17025 Accreditation: Status of laboratory accreditation, which allows a Laboratory to make and implement restricted modifications in the Scope of ISO/IEC 17025 Accreditation, as applicable, prior to the assessment by the Accreditation Body.

Further Analysis: Further Analysis occurs when a Laboratory conducts additional analysis on an "A" Sample or a "B" Sample after an analytical result for that "A" Sample or that "B" Sample has been reported by the Laboratory. There is no limitation on a Laboratory's authority to conduct repeat or confirmation analysis, or to analyze a Sample with additional Analytical Methods, or to perform any other type of additional analysis on an "A" Sample or "B" Sample prior to reporting an analytical result on that Sample. That is not considered Further Analysis.

Groom: A Covered Person who is not an Owner, Veterinarian, Trainer, or assistant Trainer but is involved in the care of a Covered Horse.

Ineligibility: See Consequences of Anti-Doping and Medication Control Rule Violations above

Initial Testing Procedure (ITP): An Analytical Testing Procedure whose purpose is to identify those Samples which may contain a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method or an elevated quantity of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

Intermediate Precision (sw): Variation in results observed when one or more factors, such as time, equipment, or operator are varied within a Laboratory. It is also referred to as inter-batch/inter-run precision.

Jockey Agents: represents a Jockey

Jockey: A rider of a Covered Horse in Covered Horseraces

Laboratory Documentation Package (LDP): The material (physical or electronic) produced by a Laboratory upon reporting of an Adverse Analytical Finding or requested by the Agency, as set forth in the Technical Document , to support an analytical result such as an Adverse Analytical Finding or an Atypical Finding. This includes abbreviated Laboratory Documentation Packages.

Laboratory Expert Group (LabEG): Group of laboratory experts responsible for providing advice, recommendations, and guidance to the Agency with respect to the overall management of anti-doping and medication control Laboratory accreditation, Laboratory disciplinary action, re-accreditation, and approval processes as well as Laboratory monitoring activities.

Laboratory Guidelines (LGs): Recommendations of Laboratory best practices provided by the Agency to address specific Laboratory operations or to provide technical requirements and guidance on interpretation and reporting of results for the analysis of specific Prohibited Substance(s), Metabolites, or Markers, and/or Prohibited Method(s) or on the application of specific Laboratory procedures.

Laboratory Internal Chain of Custody: Documentation maintained within the Laboratory to record the chronological

traceability of custody (by Person(s) or upon storage) and actions performed on the Sample and any Aliquot of the Sample taken for Analytical Testing. Laboratory Internal Chain of Custody is generally documented by a written or electronic record of the date, location, action taken, and the Person performing an action with a Sample or Aliquot.

Laboratory Standards: The Equine Laboratory Standards developed pursuant to the Act and the Protocol.

Laboratory: An Agency-accredited, or Agency-approved international laboratory applying Test Methods and processes to provide evidentiary data for the detection and/or identification of Prohibited Substances, Metabolites, Markers, or Prohibited Methods on the Prohibited List and, if applicable, quantification of a Threshold Substance in Samples of urine and other biological matrices in the context of Doping Control activities.

Last Name: a Persons legal last name aka family name

Limit of Detection (LOD): Analytical parameter of assay technical performance. Lowest concentration of an Analyte in a Sample that can be routinely detected, but not necessarily identified or quantified, under the stated Test Method conditions.

Limit of Identification (LOI): Analytical parameter of technical performance for chromatographic-mass spectrometric Confirmation Procedures. The LOI is estimated during method validation to evaluate the rate of false negative results at a certain concentration level. The LOI of a Test Method, at 5% false negative rate, for an Analyte (for which a Reference Material is available) shall be less than the MRPL. Since the LOI is an estimation of the false negative rate, Laboratories may report findings below the estimated LOI as Adverse Analytical Findings or Atypical Findings, as applicable, when the Analyte is identified in the Sample according to the criteria established in the Technical Document.

Limit of Quantification (LOQ): Analytical parameter of assay technical performance. Lowest concentration of an Analyte in a Sample that can be quantitatively determined with acceptable precision and accuracy (i.e., acceptable Measurement Uncertainty) under the stated Test Method conditions.

Major Infractions: Anti-doping and medication control rule violations under this Protocol by a Covered Person that are not Minor Infractions.

Marker: A compound, group of compounds or biological variable(s) that indicates the Use of a Prohibited Substance or Prohibited Method.

Measurement Uncertainty (MU): Parameter associated with a measurement result that characterizes the dispersion of quantity values attributed to the measure and provides confidence in the validity of the measured result.

Metabolite: Any substance produced from a Prohibited Substance by a biotransformation process.

Middle Name: a persons legal middle name

Minimum Reporting Levels: The estimated concentration of a Prohibited Substance or its Metabolite(s) or Marker(s) in a Sample below which Laboratories should not report that Sample as an Adverse Analytical Finding.

Minimum Required Performance Level (MRPL): Minimum analytical criterion of Laboratory technical performance established by the Agency. Minimum concentration at which a Laboratory is expected to consistently detect and confirm a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Prohibited Method in the routine daily operation of the Laboratory. Individual Laboratories may and are expected to achieve better performance.

Minor Infractions: Article 2.1 Presence, Article 2.2 Use, Article 2.7 Possession, and Article 2.9.3 Administration violations of this Protocol involving a Secondary Substance or a Secondary Method and for which the Agency does not allege Aggravating Circumstances. Additionally, an Article 2.5 failure to Cooperate violation; an Article 2.12 medication control rule violation; Ineligibility of a Covered Horse stemming from a violation involving a Secondary Substance or a Secondary Method; Disqualification of a Covered Horse's competitive results stemming from a violation involving a Secondary Substance or a Secondary Method only; and Ineligibility resulting from intractability.

Negative Finding: A Test result from a Laboratory which, in accordance with the effective Laboratory Standards and/or relevant Technical Document(s) and/or Technical Letter(s), concludes that no Prohibited Substance(s) or its Metabolite(s) or Marker(s) or evidence of the Use of a Prohibited Method(s), included in the requested Analytical Testing menu, were found in a Sample based on the applied Initial Testing Procedure(s) or Confirmation Procedure(s).

No Advance Notice Testing: Sample collection that takes place with no advance warning to the Covered Persons, other than to grant immediate access to the Covered Horse, and where the Covered Horse is continuously chaperoned or in a secure location (a stall, for example) from the moment of notification through Sample provision.

No Fault or Negligence: The Covered Person's establishing that they did not know or suspect and could not reasonably have known or suspected even with the exercise of utmost caution, that they had caused a Covered Horse to Use or be administered the Prohibited Substance or Prohibited Method or otherwise violate an anti-doping rule. For any violation of Article 2.1 of the Protocol, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system.

Nominated Person: A Person nominated by a Responsible Person at the time of notification or through a Whereabouts Filing to assist, witness, and consent to the Sample collection of a Covered Horse. If the Responsible Person is not present to nominate a Person, or the Nominated Person designated in the applicable Whereabouts Filing is not present or willing to assist with Sample collection, anyone employed at the stable where the Covered Horse is located by the Responsible Person or Owner (or their designees or agents) shall be the Nominated Person for that Sample collection. If no Nominated Person is promptly identified as described above, the Person who has custody or control of the Covered Horse or granted the DCO or Chaperone access to the Covered Horse shall be the Nominated Person for that Sample collection.

Non-Threshold Substance: A substance listed on the Prohibited List for which the identification, in compliance with any applicable Technical Document(s), constitutes an Adverse Analytical Finding.

Official Veterinarian: A Veterinarian employed, contracted, or appointed by a State Racing Commission or the Agency, who, among other things, is tasked with monitoring the health and welfare of Covered Horses during Covered Horseraces.

Out-of-Competition: Any period which is not during Race Day.

Owner: A Person or entity who holds an ownership or property interest in one or more Covered Horses. The term also includes the managing Owner. When an Owner is a partnership, corporation, limited liability company, syndicate or other association or entity, a managing Owner shall hold an ownership interest in the applicable Covered Horse and be designated as the individual who is liable under this Protocol as the Owner. In all circumstances in which an individual owns greater than 50% stake in a Covered Horse, that individual shall be the managing Owner. Each individual with a three percent or greater ownership or property interest in a Covered Horse must register with the Authority as an Owner of the Covered Horse. For Covered Horses claimed in a Claiming Race, the pre-claim Owner shall remain liable, to the same extent the Owner would have been liable if the Covered Horse had not been claimed, for any anti-doping or medication control rule violation resulting from a Sample collected on Race Day post-claim Race.

Paddock Judge: A person, licensed by the State Racing Commission as an official to perform the duties of a Paddock Judge

Person: A natural person or an organization or other entity

Policy: A document approved by the Commission in support of the Protocol. Compliance with a Policy (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the Policy were performed properly. Policies shall include any Standards and Technical Documents issued pursuant to the Act or Protocol.

Pony Horse: Any horse that accompanies a racehorse on the racetrack

Possession: The actual, physical Possession, or the constructive Possession (which shall be found only if the Person has exclusive control or intends to exercise control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists); provided, however, that if the Person does not have exclusive control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists, constructive Possession shall only be found if the Person knew about the presence of the Prohibited Substance or Prohibited Method and intended to exercise control over it. There shall be no anti-doping rule or medication control violation based solely on Possession if, prior to receiving notification of any kind that the Person has committed an anti-doping or medication control rule violation, the Person has taken concrete action demonstrating that the Person never intended to have Possession and has renounced Possession by explicitly declaring it to an Agency. Notwithstanding anything to the contrary in this definition, the purchase (including by any electronic or other means) of a Prohibited Substance or Prohibited Method constitutes Possession by the Person who makes the purchase.

Post-Mortem Veterinary Examination: Examination conducted following the fatality of a horse

Prefix: a title or honorarium place before a persons name such as Dr., Mr., Mrs., etc.

Presumptive Adverse Analytical Finding (PAAF): The status of a Sample test result from the Initial Testing Procedure which represents a suspicious finding, but for which a Confirmation Procedure to render a conclusive test result has not yet been performed.

Primary Method: See Regulation 4.2 (b)

Primary Substance: See Regulation 4.2 (b)

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

Prohibited Method: Any method so described on the Prohibited List.

Prohibited Substance: Any substance, or class of substances, so described on the Prohibited List.

Protocol: The Equine Anti-Doping and Medication Control Protocol.

Provisional Hearing: For purposes of Article 7, an expedited, abbreviated hearing occurring prior to an adjudication under

Article 8 to resolve a challenge to a Provisional Suspension.

Provisional Suspension: See Consequences of Anti-Doping and Medication Control Rule Violations above. With respect to Laboratories, the temporary Suspension of a Laboratory's HISA Equine Analytical Laboratory accreditation by the Agency pending a final decision by the Agency regarding the Laboratory's accreditation status.

Publicly Disclose: See Consequences of Anti-Doping and Medication Control Rule Violations above.

Race Day: The day commencing at 12:00 a.m. on the day a Covered Horse starts a Race or Workout or the Responsible Person or Nominated Person is notified for Sample collection on the day the Covered Horse is scheduled to start a Race or Workout (and prior to the Covered Horse being removed from the Race or Workout) through the end of such Race or Workout and any post-Race Sample collection process related to such Race or Workout.

Race Period: The period commencing 48 hours prior to a Covered Horse's start in any Race or Workout through the end of such Race or Workout and the Sample collection process related to such Race or Workout.

Race: A single competition in the Covered Horserace.

Racetrack: An organization licensed by a State Racing Commission to conduct Covered Horseraces.

Racing License Number: the number form the racing license that you are going to submit with your registration

Racing Official: an official licensed by the local racing commission

Reference Collection (RC): A collection of samples or isolates of known origin that may be used in the determination of the identity of an unknown substance. For example, a well-characterized sample obtained from a controlled administration or from in vitro studies in which the presence of the substance of interest has been established.

Reference Material (RM): Reference Substance or Reference Standard, which is sufficiently characterized, homogeneous and stable with respect to one or more specified properties and that has been established to be fit for its intended use in an Analytical Testing Procedure.

Registered Testing Pool: The pool of all Covered Horses, which are subject to focused Testing at all times, including outside of Race Day, as part of the Agency's test distribution plan and therefore are required to provide whereabouts information as provided in the Protocol and the Testing and Investigations Standards.

Regulatory Veterinarian: A Veterinarian employed by a State Racing Commission that has elected to enter into an agreement with the Authority.

Repeatability (sr): Variability of results obtained within a Laboratory using the same method, over a short time, using a single operator, item of equipment, etc. It is also referred to as intra-batch/intra-run precision.

Reproducibility (sR): Variability of results obtained when different Laboratories analyze Aliquots of the same Sample. Reproducibility is a property of the results obtained and represents a measurable agreement of analytical results between different Laboratories.

Responsible Person: One person (not an entity) shall be designated in the registration with the Authority as the Responsible Person. For a Covered Horse that has not yet done its first Workout (or competed in a Race, whichever is earlier), the Responsible Person shall be the Owner of the Covered Horse unless the horse is in training in another country. Once in training, the Responsible Person shall be the licensed Trainer for the Covered Horse who shall be designated and filed with the Authority. Trainer designations must be kept current with the Authority. Designation transfers must be in writing and on record with the Authority prior to the effective date, except for Claiming Races in which transfers must be recorded the same day. For Covered Horses claimed in a Claiming Race, the pre-claim Responsible Person shall remain strictly liable, to the same extent the Responsible Person would have been liable if the Covered Horse had not been claimed, for any anti-doping or medication control rule violation resulting from a Sample collected on Race Day post-claim Race. If a Covered Horse stops training for a period of time, the designation may be transferred to the Owner prior to the effective date. If the Owner is an entity, the managing Owner shall be named.

Results Management: The process encompassing the timeframe between notification, or in certain cases (e.g., Atypical Finding, Equine Biological Passport, Whereabouts Failure), such pre-notification investigation and review, through the charge until the final resolution of the matter, including the end of the first instance adjudication process and any appeals (if an appeal was lodged).

Revocation: The permanent withdrawal of a Laboratory's HISA Equine Analytical Laboratory accreditation by the Agency.

Risk Assessment: The assessment of risk of doping and medication misuse conducted by the Agency used to effectively conduct test distribution planning and/or Target Testing.

ROAP – the Racing Officials Accreditation Program

Root Cause Analysis (RCA): An investigation to identify one or more fundamental cause(s) of a nonconformity based on the collection of objective evidence from an assessment of the likely factors that led to the nonconformity. The removal of a

root cause factor prevents the recurrence of the nonconformity; in contrast, removing a causal factor can improve the outcome, but it does not prevent the recurrence of the problem with certainty.

Safety Officer: A person responsible for ensuring that all activities and practices involving the training and racing of horses at the track meet required safety standards and regulatory guidelines

Sample Collection Equipment: A and B bottles, kits or containers, collection vessels, tubes or other apparatus used to collect, hold, or store a Sample at any time during and after Doping Control.

Sample Collection Personnel: A collective term for qualified officials (including, among others, DCOs, BCOs, and Chaperones) authorized by the Agency to carry out or assist with duties during Doping Control. An individual may be authorized by the Agency to hold one or more positions during Doping Control.

Sample Collection Session: All of the sequential activities that directly involve the Covered Horse from the point that initial contact is made with the Responsible Person or Nominated Person until the Covered Horse provides a Sample and leaves the Test Barn or is otherwise discharged from Sample collection obligations.

Sample or Specimen: Any biological material collected for the purposes of Doping Control.

Scratch Time: The time set by the association for the closing of applications requesting permission of the stewards to withdraw from a Race.

Scratch: The act of withdrawing an entered horse from a Race.

Secondary Method: See Regulation 4.2 (b)

Secondary Substance: See Regulation 4.2 (b)

Selectivity: The ability of the Analytical Testing Procedure to detect or identify, as applicable, the substance of interest in the Sample.

Special Event: A series of individual national Covered Horseraces conducted together under an organizing body (e.g., TOBA Graded Stakes Committee, Triple Crown Productions, Breeders' Cup Limited) and for which a significant increase of resources and Sample analyzing capacity may be required as determined by the Agency.

Stable Employee: a licensed Person working in the stable area

Stakes Race: Any Race so designated by the Racetrack at which such race is run, including, without limitation, the races comprising the Breeders' Cup World Championships and the races designated as graded stakes by the American Graded Stakes Committee of the Thoroughbred Owners and Breeders Association

Standard: See Policy.

Starting Gate Personnel: Any person licensed as an assistant starter or any person who handles a horse in the starting gate

State Racing Commission: The regulatory body established or recognized by a state or the federal government that has jurisdiction over the conduct of horseracing within the applicable State with authority to regulate, approve, or license Covered Persons and Covered Horses.

State: the state of the racing license that you are using to register as a covered person

Steward: A duly appointed racing official with powers and duties specified by statute or rules

Strict Liability: The rule which provides that under Article 2.1 and Article 2.2 it is not necessary that intent, Fault, negligence, or knowing Use be demonstrated by the Agency in order to establish an anti-doping or medication control rule violation.

Substantial Assistance: For purposes of Article 10.7.1, a Person providing Substantial Assistance must: (1) fully disclose in a signed written statement or recorded interview all information they possesses in relation to anti-doping or medication control rule violations or other proceeding described in Article 10.7, and (2) fully Cooperate with the investigation and adjudication of any case or matter related to that information, including, for example, providing an affidavit, presenting testimony at a hearing, etc., if requested to do so by an Agency or adjudication body. Further, the information provided must be credible and must comprise an important part of any case or proceeding which is initiated or, if no case or proceeding is initiated, must have provided a sufficient basis on which a case or proceeding could have been brought.

Suffix: a designation added to a persons name such as Jr. or Sr. etc.

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

Tamper Evident: Refers to having one or more indicators or barriers to entry incorporated into or, if applicable, included with the Sample Collection Equipment, which, if breached or missing or otherwise compromised, can provide visible

evidence that Tampering or Attempted Tampering of Sample Collection Equipment has occurred.

Tampering: Intentional conduct which subverts the Doping Control process, but which would not otherwise be included in the definition of Prohibited Methods. Tampering shall include, without limitation, offering or accepting a bribe to perform or fail to perform an act, preventing the collection of a Sample, affecting or making impossible the analysis of a Sample, falsifying documents submitted to an Agency or committee or adjudication body, procuring false testimony from witnesses, committing any fraudulent act upon the Agency or adjudication body to affect Results Management or the imposition of Consequences, and any other similar interference or Attempted interference with any aspect of Doping Control. Tampering shall include, absent a compelling justification, the failure of a prospective Responsible Person (or Responsible Person) to disclose to the Agency or Authority, prior to a horse becoming a Covered Horse the Use or Attempted Use of a Prohibited Substance or Prohibited Method prohibited at all times in accordance with Article 5.4 of the Protocol.

Target Testing: Selection of specific Covered Horses for Testing based on criteria set forth in the Equine Testing and Investigations Standards.

Technical Document (TD): A document published containing mandatory technical requirements provided by the Agency for Laboratories on specific anti-doping and medication control topics.

Technical Letter (TL): A document published containing mandatory technical requirements provided by the Agency from time to time (ad-hoc) to address particular issues on the analysis, interpretation, and reporting of specific Prohibited Substance(s), Metabolites, Markers, and/or Prohibited Method(s) or on the application of specific Laboratory procedures.

Technical Note (TN): Technical guidance provided by the Agency to Laboratories on the performance of specific Laboratory methods or procedures.

Test Barn: A designated facility (or location) where the collection of Samples takes place by Sample Collection Personnel, typically on Race Day.

Test Method: Analytical Testing Procedure, Analytical Method.

Testing and Investigations Standards: The Equine Testing and Investigations Standards developed pursuant to the Act and the Protocol.

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

The cell phone number you want to receive notifications, message and calls from HISA. It is your responsibility to keep this number up to date

The city portion of your mailing address where you want to receive physical mail from HISA. It is your responsibility to keep your mailing address up to date

The country portion of your mailing address where you want to receive physical mail from HISA. It is your responsibility to keep your mailing address up to date

The email address you want to receive notifications and message sent from HISA. It is your responsibility to keep this address up to date

The state or province portion of your mailing address where you want to receive physical mail from HISA. It is your responsibility to keep your mailing address up to date

The street portion of your mailing address where you want to receive physical mail from HISA. It is your responsibility to keep your mailing address up to date

The zip or postal code portion of your mailing address where you want to receive physical mail from HISA. It is your responsibility to keep your mailing address up to date

Threshold Substance: A Prohibited Substance, Metabolite or Marker of a Prohibited Substance that fulfills the criteria for a Threshold, for which the identification and quantitative determination (e.g., concentration, ratio, score) in excess of a pre-determined Decision Limit, or, when applicable, the establishment of an exogenous origin, constitutes an Adverse Analytical Finding.

Threshold: The maximum permissible level of the concentration, ratio, or score for a Threshold Substance in a Sample. The Threshold is used to establish the Decision Limit for reporting an Adverse Analytical Finding or Atypical Finding for a Threshold Substance. Thresholds can only be adopted for (i) substances endogenous to the horse, and (ii) substances arising from plants traditionally grazed or harvested as equine feed.

Trafficking: Selling, giving, transporting, sending, delivering or distributing (or Possessing for any such purpose) a Prohibited Substance or Prohibited Method (either physically or by any electronic or other means) by a Covered Person to any third party; provided, however, this definition shall not include the actions of bona fide medical personnel involving a Prohibited Substance used for genuine and legal therapeutic purposes or other acceptable justification, and shall not

include actions involving Prohibited Substances which are prohibited on Race Day only unless the circumstances as a whole demonstrate such Prohibited Substances are not intended for genuine and legal therapeutic purposes or are intended to impact sport performance.

Trainer: A Person engaged in the training of Covered Horses

Training Facility: A location that is not a Racetrack licensed by a State Racing Commission that operates primarily to house Covered Horses and conduct Workouts

Treatment: Any substance, medication, supplement, feed additive, etc. that is not normal food or water.

Unsuccessful Attempt Report: A detailed report of an unsuccessful attempt to collect a Sample from a Covered Horse setting out the date of the attempt, the location visited, the exact arrival and departure times at the location, the steps taken at the location to try to find the Covered Horse (including details of any contact made with Persons), and any other relevant details about the attempt.

Use: The utilization, application, ingestion, injection, or consumption by any means whatsoever of any Prohibited Substance or Prohibited Method in a Covered Horse.

Vendor: a vendor that is licensed to be on the backside of a race track

Veterinarian: A licensed veterinarian who provides veterinarian services to Covered Horses and who, as a prerequisite to providing veterinarian services to Covered Horses, has registered with the Authority.

Veterinary Technician: a technician that works for a Veterinarian

Whereabouts Failure: The Failure to Comply with the Whereabouts Policy by failing to timely, accurately, and completely provide and update the required whereabouts information and/or for a Covered Horse being unavailable for Testing due to inaccurate information provided in a Whereabouts Filing.

Whereabouts Filing: Information provided by or on behalf of a Covered Horse in the Registered Testing Pool that sets out the Covered Horse’s whereabouts as described in the Whereabouts Policy.

Whereabouts Policy: The Equine Whereabouts Policy developed pursuant to the Act and the Protocol.

Workout: An official timed running of a Covered Horse over a predetermined distance not associated with a Race, including a Covered Horse’s first qualifying Race.

Your Date of Birth

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.

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.

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.

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.

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:

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

2000 RACETRACK SAFETY PROGRAM.

2010 DEFINITIONS.

When used in the Rule 2000 Series:

Workout means an official timed running of a Covered Horse over a predetermined distance not associated with a Race.

Veterinarian means a licensed veterinarian who provides veterinarian services to Covered Horses and who, as a prerequisite to providing veterinarian services to Covered Horses, has registered with the Authority.

Training Facility means a location that is not a Racetrack that operates primarily to house Covered Horses and conduct Workouts.

Trainer means a Person engaged in the training of Covered Horses.

State Racing Commission means the regulatory body established or recognized by a state or the federal government with authority to regulate, approve, or license Covered Persons and Covered Horses.

Starting Gate Person means any individual licensed as an assistant starter or any individual who handles Horses in the starting gate.

Shock Wave Therapy means extracorporeal shock wave therapy or radial pulse wave therapy.

Safety Officer means an individual designated as, and having the responsibilities of, a Safety Officer as set forth in Rule 2136.

Safety Director means an individual designated as, and having the responsibilities of, a Safety Director as set forth in Rule 2131.

ROAP means the Racing Officials Accreditation Program.

Responsible Person means the individual designated in the registration with the Authority as the Responsible Person in accordance with the following:

(01) For a Covered Horse that has not yet performed its first Workout (or competed in a Race, whichever is earlier), the Responsible Person shall be the Owner of the Covered Horse unless the Horse is in training in another country.

(02) Once in training, the Responsible Person shall be the licensed Trainer for the Covered Horse. The licensed Trainer's designation as the Responsible Person shall be filed with the Authority. The Trainer designation must be kept current with the Authority. Designation transfers must be in writing and on record with the Authority prior to the effective date of the transfer, except for claiming Races in which transfers must be recorded the same day.

(03) If a Covered Horse ceases training for a period of time, the designation may be transferred to the Owner prior to the effective date.

(04) If the Owner is an entity, the managing Owner shall be named.

Regulatory Veterinarian means a Veterinarian employed, contracted, or appointed by a State Racing Commission, Racetrack, or the Agency, who in addition to other duties, is responsible for monitoring the health and welfare of Covered Horses during Covered Horseraces.

Racetrack Safety and Welfare Committee means the committee established pursuant to Rule 2121.

Racetrack Safety Committee means the committee established pursuant to 15 USC 3052(c)(2).

Racetrack Safety Accreditation or Accreditation means the process for achieving, and the issuance of, safety Accreditation to a Racetrack in accordance with the Rule 2100 Series.

Racetrack means an organization licensed by a State Racing Commission to conduct Covered

Horseraces.

Race Meet means the entire period granted by the State Racing Commission to a Racetrack for the conduct of Covered Horseraces on the Racetrack's premises.

Protocol means the Equine Anti-Doping and Medication Control Protocol set forth in the Rule 3000 Series.

Prohibited Substance means any substance, or class of substances, so described on the Prohibited List.

Prohibited List means the Equine Prohibited List identifying the Prohibited Substances and Prohibited Methods as set forth in the Rule 4000 Series.

Program Effective Date means July 1, 2022.

Person means a natural person or an organization or other entity.

Owner means a Person or entity who holds an ownership or property interest in one or more Covered Horses.

Out-of-Competition means any period which is not during race day.

Medical Director means an individual designated as Medical Director in accordance with the provisions of Rule 2132.

Lead Veterinarian means any Veterinarian appointed pursuant to Rule 2134(b).

Jockey means a rider of a Covered Horse in a Covered Horserace.

Groom means a Covered Person who is not an Owner, Veterinarian, Trainer, or assistant Trainer but is involved in the care of a Covered Horse.

Covered Persons means all Trainers, Owners, breeders, Jockeys, Racetracks, Veterinarians, and Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such persons and other Horse support personnel who are engaged in the care, training, or racing of Covered Horses.

Covered Horserace or Race means any horserace involving Covered Horses that has a substantial relation to interstate commerce, including any Thoroughbred horserace that is the subject of interstate off-track or advance deposit wagers.

Unless the context otherwise requires, Horse and Covered Horse shall have correlative meanings for purposes of this Rule 2000 Series.

Covered Horse means any thoroughbred horse, or any other horse made subject to the Act by election of the applicable State Racing Commission or the breed governing organization for such horse, beginning on the earlier of:

(01) the date of the Horse's first timed and reported workout at a Racetrack;

(02) the date of the Horse's first timed and reported workout at a Training Facility;

(03) the date of the Horse's entry in a Covered Horserace; or

(04) the date of the Horse's nomination for a Covered Horserace, and ending on the date on which the Agency receives written notice that the Horse has been retired in accordance with the Protocol.

Concussion means an injury to the brain that results in temporary loss of normal brain function.

Claiming Race means a Race in which a Horse after leaving the starting gate may be claimed in accordance with the rules and regulations of the applicable State Racing Commission.

Claim means, in the context of a Claiming Race, the purchase of a Covered Horse for a designated amount.

Bled means that blood from one or both nostrils of a Horse has been observed after exercise.

Authority means the Horseracing Integrity and Safety Authority.

Attending Veterinarian means a Veterinarian hired by the Trainer or Owner.

Association Veterinarian means a Veterinarian employed by a Racetrack.

Act means the Horseracing Integrity and Safety Act of 2020.

2100 RACETRACK ACCREDITATION.

2101 GENERAL.

(a) The Racetrack Safety Committee and the Authority shall oversee Racetrack Safety Accreditation in accordance with provisions of this Rule 2100 Series. The Racetrack Safety Committee may also adopt best practices and guidance in accordance with the Act and the rules and regulations promulgated thereunder to provide further guidance to the Racetracks in the Accreditation Process.

(b) All Racetracks are required to seek and meet the requirements of Racetrack Safety Accreditation with the Racetrack Safety Committee in accordance with the provisions of this Rule 2100 Series.

2110 ACCREDITATION PROCESS.

2111 INTERIM AND PROVISIONAL ACCREDITATION.

(a) Interim Accreditation.

(01) A Racetrack that is accredited by the National Thoroughbred Racing Association as of the Program Effective Date shall be granted interim Racetrack Safety Accreditation, which shall be effective until the later of:

(i) such time as the Racetrack Safety Committee completes an Accreditation assessment under Rule 2112 with respect to such Racetrack; or

(ii) the time period established by the Authority under Rule 2114(a).

(b) Provisional Accreditation.

(01) A Racetrack that is not accredited by the National Thoroughbred Racing Association as of the Program Effective Date shall be granted provisional Racetrack Safety Accreditation, which shall be effective until the later of:

(i) such time as the Racetrack Safety Committee completes an Accreditation assessment under Rule 2112 with respect to such Racetrack; or

(ii) the time period established by the Authority under Rule 2114(b).

(02) The Authority may at any time upon reasonable notice require a Racetrack with provisional Racetrack Safety Accreditation to report on its progress in achieving Accreditation. The Authority may request any additional information from the Racetrack necessary to make its determination and may conduct unannounced on-site inspections at any time.

2112 ACCREDITATION ASSESSMENT.

(a) Upon the initiation of an Accreditation assessment by the Racetrack Safety Committee, the subject Racetrack shall submit or provide access to any relevant information and documentation requested by the Racetrack Safety Committee. The Racetrack Safety Committee may request any additional information and documentation required for the assessment and may propound

additional written questions or inquiries to the Racetrack. The Racetrack shall respond in writing to all additional questions and inquiries within sixty (60) days of receipt of any additional questions and inquires.

(b) After review of all information submitted by the Racetrack under paragraph (a), the Racetrack Safety Committee shall conduct an on-site inspection of the Racetrack. The Racetrack Safety Committee shall then prepare a post-inspection report identifying any aspects of the Racetrack's operations that are not in compliance with the requirements of this Rule 2100 Series.

(c) Within sixty (60) days of the Racetrack's receipt of the post-inspection report under paragraph (b), the Racetrack shall respond in writing to the Racetrack Safety Committee setting forth all actions to be taken by the Racetrack to remedy the areas of non-compliance identified in the post-inspection report, and the timeframes necessary for implementation of such remedial actions.

(d) The Racetrack Safety Committee shall assess the Racetrack's response and make a written recommendation to the Authority whether to issue or deny Accreditation or provisional Accreditation of the Racetrack.

2113 ISSUANCE OF ACCREDITATION.

(a) The Authority shall determine whether a Racetrack is entitled to Accreditation by evaluating compliance with the requirements set forth in this Rule 2100 Series.

(b) In determining whether to grant, renew or deny Accreditation to a Racetrack, the Authority shall review all information submitted by the Racetrack and the Racing Safety Committee's recommendation.

2114 EFFECTIVE PERIODS OF ACCREDITATION.

(a) Accreditation.

(01) Accreditation shall be effective for a period of three (3) years.

(02) The Authority may modify the Accreditation period to a period of one (1) to seven (7) years if the Authority determines that such modified period will be consistent with the requirements of Accreditation outlined in this Rule 2100 Series.

(b) Provisional Accreditation.

(01) Provisional Accreditation shall be effective for an initial period of one (1) year.

(02) Upon the expiration of the initial one (1) year period referenced in paragraph (1) above, provisional Accreditation may be extended for additional one (1) year periods if the Authority determines that the subject Racetrack is continuing to undertake good faith efforts to comply with the requirements of this Rule 2100 series and achieve Accreditation.

2115 ANNUAL REPORTING.

All Racetracks granted Accreditation under these Rules shall participate in ongoing reporting and review to the Racetrack Safety Committee. All accredited Racetracks shall, by December 31st of each calendar year, submit satisfactory annual reports to the Racetrack Safety Committee demonstrating compliance with all Accreditation requirements.

2116 SUSPENSION AND REVOCATION OF ACCREDITATION.

(a) An accredited Racetrack that is in material noncompliance with the Accreditation requirements, after having received notice of the noncompliance and been given a reasonable opportunity to remedy the noncompliance, may have its Accreditation suspended by the Authority.

(b) A provisionally accredited Racetrack that is in material noncompliance with the provisional

Accreditation requirements, after having received notice of the noncompliance and been given a reasonable opportunity to remedy the noncompliance, may have its provisional Accreditation suspended by the Authority.

(c) A Racetrack under suspension shall not conduct any Covered Horserace.

(d) A suspended Racetrack that fails to remedy the noncompliance in a reasonable time may have its Accreditation or provisional Accreditation revoked by the Authority.

2120 ACCREDITATION REQUIREMENTS.

2121 RACETRACK SAFETY AND WELFARE COMMITTEE.

(a) General. The Racetracks in each state shall form a Racetrack Safety and Welfare Committee to review the circumstances around fatalities, injuries, and racetrack safety issues with the goal of identifying possible contributing risk factors that can be mitigated.

(b) Composition. The composition of the Racetrack Safety and Welfare Committee may vary among jurisdictions, provided that each Racetrack Safety and Welfare Committee shall include, at a minimum, the following:

(01) Regulatory Veterinarian;

(02) Association Veterinarian;

(03) Medical Director;

(04) Safety Officer or steward, subject to the applicable State Racing Commission electing to enter into an agreement with the Authority if such individual is employed by the State Racing Commission;

(05) Horsemen’s representative;

(06) Jockey;

(07) Trainer;

(08) racing secretary, and

(09) racetrack superintendent.

(c) The Regulatory Veterinarian shall chair the Racetrack Safety and Welfare Committee.

(d) If the Safety Director is not a committee member, the Safety Director shall be an ad hoc member of the Racetrack Safety and Welfare Committee.

(e) Responsibilities. The Racetrack Safety and Welfare Committee shall be responsible for:

(01) Review of all equine catastrophic injuries and the circumstances surrounding those injuries, including, at a minimum:

(i) interviews with Trainers, Jockeys, exercise riders, and Attending Veterinarians, and when appropriate, a qualified human health provider;

(ii) examination of past performances, Workouts, pre-race inspection findings, necropsy examination findings, and Trainer and Veterinary treatment records;

(iii) review of Race or training video footage, if applicable;

(iv) review of racetrack surface conditions and weather information;

(v) convening a meeting with connections of the Covered Horse and other interested Persons, including, at a minimum, the Regulatory Veterinarian, Trainer, and Attending Veterinarian, and if applicable, the Jockey, exercise rider, and racetrack superintendent to:

(A) convey the findings of the review;

(B) acquire additional information useful for developing strategies for injury prevention; and

(C) provide continuing education or continuing education recommendations related to cause of equine injury, if available, to persons related to the applicable Covered Horse.

(vi) evaluation of factors that may have contributed to injuries;

(vii) evaluation of the effectiveness of protocols and procedures for managing the equine injury scenario; and

(viii) developing strategies to mitigate identified factors that may have contributed to the injury.

(02) Review of all environmental factors related to racing and training that may have contributed to human injury occurrences including:

(i) evaluation of external factors that may have contributed to injuries;

(ii) development of strategies to mitigate identified factors that may have contributed to the injury;

(iii) evaluation of the effectiveness of protocols and procedures for managing human injury occurrences;

(03) Consideration of Racetrack safety issues brought to the Racetrack Safety and Welfare Committee's attention;

(04) Summary review of all injuries and considerations to review existing practices,

(05) Development of strategies to reduce or mitigate injury occurrences,

(06) Enhancement of the identification of Horses or conditions for which intervention is warranted; and

(07) Enhancement of racetrack safety for equine and human participants.

(08) Preparation and submission of a report that summarizes the findings of the Racetrack Safety and Welfare Committee under this paragraph (c) to the Authority within sixty (60) days of the end of the applicable Race Meet, unless the Racetrack Safety Committee requires earlier submission.

2130 REQUIRED SAFETY PERSONNEL.

2131 SAFETY DIRECTOR.

(a) The Safety Director shall oversee equine safety, racetrack safety, and risk management and injury prevention at each Racetrack in accordance with the provisions of this Rule. The Safety Director may at the same time serve in the applicable jurisdiction as a Regulatory Veterinarian or Safety Officer. Subject to the approval of the Racetrack Safety Committee, the Safety Director may be shared within and among jurisdictions.

(b) If the applicable State Racing Commission does not enter into an agreement with the Authority, then the Racetracks in such jurisdiction shall implement the requirements set forth in this Rule, subject to the Racetrack Safety Committee's approval of the individual named as Safety Director.

(c) The Safety Director shall be responsible for:

(01) Creating a culture of safety for Horses, riders, and Racetrack personnel;

(02) Overseeing all aspects of equine safety, racetrack safety, and safety of personnel working with Horses by ensuring that all activities and practices involving the training and racing of Horses at the track meet required safety standards;

(03) Implementing a risk management and injury prevention program under the oversight of the Racetrack Safety Committee;

(04) Providing guidance to Attending Veterinarians on safety issues;

(05) Maintaining and annually reviewing standard operating procedures and protocols;

(06) Coordinating and overseeing emergency drills that include equine injury and starting gate malfunction;

(07) Reporting all equine injuries and fatalities to the Authority within seventy-two (72) hours of injury; and

(08) Interacting with the Authority concerning Racetrack Safety Accreditation compliance.

2132 MEDICAL DIRECTOR.

(a) The Medical Director shall oversee the care and organization of the medical needs of Jockeys. The Medical Director shall be either a licensed physician or a board-certified athletic trainer. Subject to the approval of the Racetrack Safety Committee, the Medical Director may be shared within and among jurisdictions.

(b) In any jurisdiction where the applicable State Racing Commission does not elect to enter into an agreement with the Authority to establish a Medical Director consistent with this Rule, the Authority shall appoint and employ a Medical Director to serve as Medical Director in that jurisdiction. The Racetracks in the applicable jurisdiction shall reimburse the Authority for all costs associated with the employment of the Medical Director. Such reimbursement shall be shared by the Racetracks in such jurisdiction proportionally by total handle wagered in the applicable state in the prior calendar year.

(c) The Medical Director shall:

(01) Identify professional medical providers and referral networks that are licensed and certified to oversee racetrack emergency services, which may include, hospital affiliations, nursing staff, EMT service and paramedics, internists, surgeons, family practitioners, dentists, athletic trainers, or psychiatrists;

(02) Make medical provider contact information readily available for ease of communication and immediate coordination of care for any medical event;

(03) Report all human injuries to the Authority within seventy-two (72) hours of injury;

(04) Coordinate and oversee a plan for on-site medical care, including provisions for emergency medical facilities and staffing;

(05) Implement an emergency drill for a rider injury;

(06) Coordinate and oversee a comprehensive plan for transportation of an injured rider to the nearest Trauma Level One or Two facility;

(07) Coordinate and oversee a plan for transportation of an injured rider to the Racetrack's first aid facility;

(08) Ensure compliance with mandatory annual rider physical examination requirements to indicate readiness to ride for Jockeys, and document compliance to the Authority;

(09) Exercise oversight of medical standards, including the minimum criteria for riding fitness;

(10) Certify a rider's fitness to resume riding after any on-track incident that may impair the rider's reflexes, decision-making or ability to maintain control of his or her Horse in a race;

(11) Implement the program for Concussion evaluation, rider exclusion and clearance, and return to ride protocol;

(12) Develop in writing, subject to annual review and revision as necessary, the Racetrack's Emergency Action Plan, which shall include readiness for medical needs of racing participants, workers, and spectators; and

(13) Work with local, state, and federal regulators to standardize the approach and response to pandemic-related issues among riders, workers, and spectators.

2133 STEWARDS.

(a) In states where the applicable State Racing Commission elects to enter into an agreement with the Authority, the stewards, in addition to their duties under state law, shall enforce the safety regulations set forth in the Rule 2200 Series.

(b) To qualify for appointment as a steward, the appointee shall meet the experience, education, and examination requirements necessary to be accredited by the ROAP and be in good standing with all racing jurisdictions.

(c) The requirements of this Rule for any steward employed by a State Racing Commission are subject to the applicable State Racing Commission electing to enter into an agreement with the Authority. If the applicable State Racing Commission does not enter into such an agreement, the Racetracks in the jurisdiction shall implement the requirements set forth in this Rule, subject to the Racetrack Safety Committee's approval of the individuals named as stewards by the Racetracks. The stewards named by the Racetracks shall enforce only the safety regulations set forth in the Rule 2200 Series.

2134 REGULATORY VETERINARIAN.

(a) The Regulatory Veterinarian shall:

(01) Subject to the provisions of paragraph (b) below, be employed by the State Racing Commission or similar agency having jurisdictional authority;

(02) be licensed to practice in the applicable jurisdiction;

(03) refuse employment or payment, directly or indirectly, from any Owner or Trainer of a Horse racing or intending to race in the jurisdiction while employed as a Regulatory Veterinarian;

(04) refrain from directly treating or prescribing for any Horse within the applicable jurisdiction except in cases of emergency, accident, or injury; and

(05) Regulatory Veterinarians must be trained, and their proficiency verified, in identifying and stabilizing common musculoskeletal injuries.

(b) In any jurisdiction where the applicable State Racing Commission does not elect to enter into an agreement with the Authority to establish a Regulatory Veterinarian consistent with this Rule, the Authority shall employ a Veterinarian to serve as the Lead Veterinarian in such jurisdiction. The Lead Veterinarian shall perform all of the duties, obligations and responsibilities of the Regulatory Veterinarian in these regulations. The Racetracks in the applicable jurisdiction shall reimburse the Authority for all costs associated with the employment of the Lead Veterinarian. The reimbursement shall be shared by the Racetracks in the jurisdiction proportionally by total handle wagered in the applicable state in the prior calendar year.

2135 RESPONSIBILITIES AND DUTIES OF REGULATORY VETERINARIAN.

(a) The Regulatory Veterinarian shall have the following responsibilities and duties:

(01) notify the stewards of any Horse deemed unsafe to be raced, or a Horse that it would be

inhumane to allow to race;

(02) conduct pre-race inspections on all potential starters on race day;

(03) inspect any Horse when there is a question as to the physical condition of such Horse independent of the Horse's entry status;

(04) be present in the paddock during saddling, on the racetrack during the post parade, and present at the starting gate until the Horses are dispatched from the starting gate for the Race;

(05) scratch any Horse that is, in the opinion of the Regulatory Veterinarian, injured, ill, or otherwise unable to compete due to a medical or health-related condition;

(06) inspect any Horse which appears to be in physical distress during the Race or at the finish of the Race;

(07) provide emergency medical care to Horses injured while racing and effect case transfer to the Attending Veterinarian;

(08) be authorized to euthanize, consistent with the current version of the AVMA Guidelines for the Euthanasia of Animals, any Horse deemed to be so seriously injured that it is in the best interests of the Horse to so act;

(09) report to the Safety Director the names of all Horses euthanized or which otherwise die at the meeting and the reasons therefor;

(10) maintain the Veterinarians' List of Horses ineligible to race and notify the stewards of the identities of all Horses placed on the Veterinarians' List; and

(11) collaborate with the Safety Director, Chief Veterinarian of the State Department of Agriculture, and other regulatory agencies to take measures to control communicable or reportable equine diseases.

(b) If the Regulatory Veterinarian and his or her staff are unable to fulfill any of the duties described in paragraph (a) of this Rule, such duties may, at the request of the Regulatory Veterinarian, be performed by an Association Veterinarian. In such case, the Association Veterinarian shall be responsible for adhering to and upholding the rules and regulations of the Authority and the State Racing Commission.

(c) The Regulatory Veterinarian, and any Association Veterinarian exercising duties of the Regulatory Veterinarian as provided in paragraph (b) above, are authorized to:

(01) access any and all Horses housed on Racetrack grounds regardless of entry status;

(02) perform inspections of any Horse at any time;

(03) observe Horses during training activities and Workouts;

(04) perform pre-Race veterinary inspections and post-Race observations; and

(05) Place a Horse on the Veterinarians' List.

(d) The Regulatory Veterinarian shall have jurisdiction over the Attending Veterinarians within the grounds of the Racetrack and shall review and consult with the stewards, and State Racing Commission regarding the State Racing Commission license applications of Attending Veterinarians, veterinary technicians or assistants, vendors of medical supplies and equipment, and non-Veterinarian health care providers. The authority and responsibilities of the Regulatory Veterinarian under this paragraph (d) shall not be performed by an Association Veterinarian pursuant to paragraph (b) of this Rule.

2136 RACETRACK SAFETY OFFICER.

(a) Each Racetrack shall have a Safety Officer to ensure that all activities and practices involving the training and racing of Horses at the Racetrack meet required safety standards and regulatory guidelines. The Safety Officer may also be a steward.

(b) The Safety Officer shall:

(01) Monitor daily stable area activities and practices in the barn area and on the racetrack for compliance with the applicable State Racing Commission safety regulations and the Rules of the Authority;

(02) Conduct pre-Race Meet racetrack safety inspections;

(03) Monitor outrider compliance with Racetrack rules during morning workouts;

(04) Monitor starting gate procedures;

(05) Monitor ambulance and medical personnel protocols for Horses and riders;

(06) Assist Regulatory Veterinarians with follow-up on Horses barred from training or vanned off during training and racing;

(07) Review ship-in and ship-out lists and undertake appropriate investigations;

(08) Conduct random license checks in the stable area;

(09) Conduct random barn inspections to monitor safety and regulatory compliance, including fire safety regulations;

(10) Conduct random inspections to verify acceptable management, equine husbandry, and veterinary practices;

(11) Advise stewards of all planned and random inspections;

(12) Enforce fire safety rules in the stable area;

(13) Serve as a member or ad hoc member of the Racetrack Safety and Welfare Committee; and

(14) Make recommendations to Racetrack management and racing officials to ensure the welfare of Horses and riders, the integrity of racing, and compliance with applicable horse racing laws and regulations.

2140 RACEHORSE INSPECTIONS AND MONITORING.

2141 VETERINARY INSPECTIONS.

(a) Veterinary inspections shall be performed by the Regulatory Veterinarians on all Horses entered in a Race. Such inspections shall include the items listed in Rule 2142.

(b) If, prior to starting a Race, a Horse is determined to be unfit for competition, or if the Regulatory Veterinarian is unable to make a determination of racing soundness, the Regulatory Veterinarian shall notify the stewards that the Horse is scratched. Regulatory Veterinarians shall have the unconditional authority to scratch a Covered Horse from a Race.

2142 ASSESSMENT OF RACING SOUNDNESS.

(a) Post-entry screening. The Regulatory Veterinarian shall perform post-entry screenings of previous pre-Race inspection findings of entered Horses to identify Horses that may be at increased risk for injury. The Regulatory Veterinarian shall review past performances, lay-ups (more than sixty (60) days without a timed Workout or Race), last thirty (30) days medical history, previous injury and lameness diagnostics, intra-articular corticosteroid injections, previous surgery, and individual Horse risk factors.

(b) Pre-race veterinary inspection. Every Horse entered to participate in a Covered Horserace shall be subjected to inspection by a Regulatory Veterinarian prior to starting in the Race for which it is entered on race day not later than one (1) hour prior to scratch time for the Race in which the Horse is to compete.

(01) The Trainer of each Horse or a representative of the Trainer who is knowledgeable about the Horse and able to communicate with the Regulatory Veterinarian must present the Horse for inspection. Horses presented for inspection must have bandages removed, and the legs must be clean and dry. Prior to inspection, Horses may not be placed in ice and no device or substance shall be applied to the Horse that impedes veterinary clinical assessment.

(02) The Regulatory Veterinarian's inspection of each Horse prior to participating in a Race shall include, at a minimum, the following:

(i) Identification of the Horse.

(ii) Ascertainment of the sex of the Horse.

(iii) Performance of an overall inspection of the entire Horse, assessing general appearance, behavior, disposition, posture, and body condition.

(iv) Observation of the Horse jogging in hand, moving towards and away from the Veterinarian so that both hind-end and front-end motion can be evaluated.

(v) Performance of a digital palpation on both distal forelimbs.

(vi) Placement of the Horse on the Veterinarian's List if the Horse does not jog sound or warm up to the Regulatory Veterinarian's satisfaction

(vii) Visual observation in the paddock and saddling area, during the parade to post, and at the starting gate.

(viii) Any other inspection deemed necessary by the Regulatory Veterinarian, including Jockey consultation for the Jockey's mount.

(03) A report summarizing the results of a pre-Race inspection under this paragraph (a) shall be submitted to the Authority on the day of the inspection.

(c) Post-race assessment. Post-Race visual observations shall be performed by a Regulatory Veterinarian on all Horses leaving the racetrack at the conclusion of every Race.

(01) If a Horse is determined to have Bled or to be physically distressed, medically compromised, injured, or unsound at any time before exiting the racetrack or leaving the test barn, the Horse shall be placed on the Veterinarians' List and the Regulatory Veterinarian shall document post-race inspection findings to the Authority.

(02) If a Horse is determined to have skin lacerations, swellings, or welts that resulted from crop use, the stewards and Attending Veterinarian shall be notified, and the information documented to the Authority.

(d) Training. Regulatory Veterinarians may observe Horses during training activities. Horses deemed physically distressed, medically compromised, injured, or unsound may be placed on the Veterinarians' List and reported to the Authority.

2143 RACEHORSE MONITORING.

(a) All Horses, including stable ponies, entering the Racetrack grounds must have proof of health certificate and required vaccinations, which shall include:

(01) Certificate of veterinary inspection within the prior five (5) days or fewer days if high risk situations dictate;

(02) Verification of EEE/WEE/WNV (encephalitides), rabies, and tetanus vaccinations within the prior twelve (12) months;

(03) Verification of Influenza and Rhinopneumonitis vaccinations within the prior 180 days or fewer days if high risk situations dictate; and

(04) Verification of Negative Equine Infectious Anemia (Coggins) Test within the calendar year or in a shorter period of time if high risk situations dictate.

(b) Each Racetrack shall submit the following information to the Authority with respect to each Horse on its grounds:

(01) Horse identification;

(02) Origin of Horse;

(03) Date of entry;

(04) Verification of certificate of veterinary inspection; and

(05) Verification of vaccinations.

(c) Each Racetrack shall submit the following information to the Authority with respect to each Horse leaving its grounds:

(01) Horse identification;

(02) Intended destination;

(03) Reason for departure;

(04) Date of exit;

(05) Vehicle license plate; and

(06) Transporter.

(d) Horses moving interstate must meet the entry requirements of the destination state, the State Racing Commission in the destination state, and the individual Racetracks or Training Facilities to which the horse is being shipped in the destination state.

2150 RACETRACK AND RACING SURFACE MONITORING AND MAINTENANCE.

2151 DATA COLLECTION, RECORDKEEPING AND SUBMISSION.

(a) Racetracks shall have data collection protocols in place to assist in the proper and consistent maintenance of all racing and training surfaces. Racing and training surface testing and maintenance should be performed based on the Racetrack's written standard operating procedures which are reviewed annually and updated as needed. The Racetrack Safety Committee, or its designees, shall develop and annually update a Racetrack Surface Standard Practices Document.

(b) All Racetrack design records, racing and training surface maintenance records, surface material tests, and daily tests data shall be recorded in a format acceptable to the Authority and shall be submitted to the Authority. Any test results shall be submitted to the Authority within one (1) week of the test results.

2152 TESTING METHODS.

(a) Surface test methods and surface material test methods must be documented and consistent with testing standards from internationally recognized standards organizations including ASTM International, American Society of Agricultural and Biological Engineers or other relevant international standards, and when possible for unpublished standards, methods consistent with those documented by the Racing Surfaces Testing Laboratory.

2153 RACETRACK FACILITIES.

The Racetrack facilities must be designed, constructed and maintained as provided in this Rule to provide for the safety of Covered Persons and Covered Horses.

(a) Rails.

(01) Racetracks shall have inside, outside, and gap rails designed, constructed, and maintained to provide for the safety of Jockeys and Horses.

(02) Objects within 10 feet of the inside rail shall be flexible enough to collapse upon impact of a Horse or rider, or sufficiently padded as to prevent injury.

(03) Rails shall be inspected prior to each Race Meet and daily during training and racing events.

(b) Gaps.

(01) All gaps must be clearly marked, must have protective padding covering any sharp edges or unique angles, and have proper mechanisms to allow for secure closure when needed.

(02) Main gaps and on-gaps should include signage with safety rules, Racetrack hours and other applicable rules.

(03) For Races breaking from a chute there should be sufficient temporary rail extension to prevent Horses from ducking in or out.

(c) Starting gate.

(01) All gates, and the vehicle that moves the gates, must be inspected pre-Race Meet and documented to be in proper working condition.

(02) All gates must have protective padding to ensure the safety of the Horse, Jockey, and gate personnel. Protective padding shall protect the riders and gate personnel from contact with sharp edges and help to distribute impact loads. All padding shall be designed to ensure durability for outdoor use and shall be capable of maintaining safety and physical integrity during all weather conditions.

(03) Gates and the vehicle that moves the gates shall be inspected and tested each race day before the Races and each morning before schooling to ensure proper functioning.

(04) No personnel, other than those required for steering the gate, shall ride on the gate while the gate is in motion or being transported.

(05) Racetracks shall have in place annually reviewed and documented standard operating procedures for the removal of the starting gate after the start of each Race as needed in a safe and timely manner. This plan shall also include procedures for gate removal if the primary removal mechanism fails.

(06) Every Starting Gate Person shall wear protective gear when working on or around the starting gate, including approved helmets and safety vests.

(07) If the starting gate becomes inoperable during racing hours, racing may not continue until the starting gate is brought back to safe operating standards or the inoperable gate is replaced with a properly functioning alternate gate.

(08) During racing hours, a Racetrack should ensure that sufficient assistant starters are available to safely handle each Horse entered in a Race.

(09) A Racetrack shall make at least one starting gate and one Starting Gate Person available for racehorse schooling during designated gate training hours.

(d) Emergency warning system.

(01) Each Racetrack shall have an operational emergency warning system on all racing and training tracks. The emergency warning system shall be approved by the State Racing Commission, subject to the applicable State Racing Commission electing to enter into an agreement with the Authority. If such agreement does not exist, the emergency warning system shall be approved by the Authority.

(02) The emergency warning system shall be tested bi-weekly before training or racing.

(03) During training, when the emergency warning system is activated, all persons on horseback shall slow to a walk and no one on horseback shall enter the racetrack.

(04) The Racetrack announcer shall be trained to utilize the public address system to:

(i) Warn riders of potentially dangerous situations and provide direction; and

(ii) Warn patrons of potentially dangerous situations and provide direction.

2154 RACETRACK SURFACE MONITORING.

(a) Racetracks shall provide equipment and personnel necessary to maintain the racetrack surface in a safe and consistent condition.

(b) Pre-meet inspection shall be performed on all surfaces prior to the start of each Race Meet with sufficient time allotted to facilitate corrections of any issues prior to racing. For Race (1) Meets spanning periods with significant weather variation, inspections shall be performed seasonally prior to anticipated weather changes.

(01) Inspections for dirt and synthetic surfaces shall include the following elements:

(i) Determine and document race and training track configurations and geometries, including:

(A) Geometry and slopes of straights and turns and slopes at each distance marker pole;

(B) The accuracy of distances from the finish line to the marker poles; and

(C) cushion and base geometries.

(ii) Base inspection, including windrowing and base survey, surface survey, ground penetrating radar, or other method;

(iii) Mechanical properties of racing and training tracks using a biomechanical surface tester shall be determined and documented;

(iv) Surface material samples of racing and training tracks shall be analyzed for material composition pursuant to the Racetrack Surface Standard Practices Document; and

(v) Corrective measures to address issues under paragraphs (i) through (iv) above.

(02) Inspections for turf surfaces shall include the following elements:

(i) Determine and document racetrack configuration and geometry, including:

(A) Geometry and slopes of straights and turns and slopes at each distance marker pole;

(B) irrigation systems;

(C) turf profile; and

(D) ensure distances from the finish line to the marker poles are correct.

(ii) Document turf species;

(iii) Mechanical properties of racing and training tracks using a surface tester should be determined and documented;

(iv) Surface material samples of racing and training tracks shall be analyzed for material composition pursuant to the Racetrack Surface Standard Practices Document;

(v) The irrigation system must be tested to evaluate function of all components and water coverage including gaps and overlap; and

(vi) Corrective measures to address issues under paragraphs (i) through (iv) above.

(c) Daily measurements shall be taken at the beginning of all daily training and racing sessions for racing and training tracks taken at each ¼ mile marker pole at locations 5 and 15 feet outside the inside rail.

(01) For dirt and synthetic surfaces, such daily measurements shall include:

(i) Moisture content;

(ii) Cushion depth; and

(iii) Weather conditions and precipitation at 15-minute intervals from a national or local weather service.

(02) For turf surfaces, such daily measurements shall include:

(i) Moisture content; and

(ii) Penetration and shear properties.

(d) Surface equipment inventory, surface maintenance logs, and surface material addition or renovation logs shall be maintained and submitted to the Authority.

(01) Daily surface maintenance logs should include equipment used, direction of travel, water administration.

(02) Documentation of the source, timing, quantity, and method of all additions to the surfaces shall be submitted to the Authority.

2160 EMERGENCY PREPAREDNESS.

2161 EMERGENCY DRILLS.

Emergency protocols shall be reviewed, and drills shall be conducted, prior to the beginning of each Race Meet for purposes of demonstrating the Racetrack's proficiency in managing the following emergencies:

(a) Starting gate malfunction;

(b) Paddock emergencies;

(c) Equine injury;

(d) Jockey injury;

(e) Loose Horse;

(f) Fire;

(g) Hazardous weather condition; and

(h) Multiple injury scenarios for both Horses and Jockeys;

2162 CATASTROPHIC INJURY.

Racetracks and Training Facilities under the jurisdiction of a State Racing Commission shall have protocols in place for instances of catastrophic injury to Horses during racing and training. Protocols should include, but not be limited to requiring collection of biological samples in sufficient volume, to permit comprehensive drug testing. Planning shall include appropriate means of communication to the public

2163 FIRE SAFETY.

Racetracks and Training Facilities under the jurisdiction of a State Racing Commission shall plan for and have protocols in place for instances of fire within their enclosures. Fire and life safety inspections shall be performed in accordance with the local authority and appropriate National Fire Protection Association standards and shall be conducted at the required frequency. Racetracks shall document adherence to the applicable local fire protection authority.

2164 HAZARDOUS WEATHER.

Each Racetrack shall develop, implement, and annually review a hazardous weather protocol which shall include:

(a) Designation of the personnel responsible for monitoring weather conditions, immediately investigating any known impending threat of dangerous weather conditions and determining if conditions exist which warrant delay or cancellation of training or racing and the notification to the public of such dangerous weather conditions.

(b) Use of a designated weather watcher and a reliable source for monitoring the weather, including lightning strike distance/radius notifications.

(c) Implementation of a dangerous weather protocol, which includes for extreme heat and chill factors and air quality.

(d) Designation by the Racetrack of an official responsible for monitoring weather conditions during training and racing hours.

(e) Consideration by the Racetrack of lightning safety guidelines such as the National Athletic Trainers' Association Position Statement, or more recent evidence-based recommendations.

(f) Requirements that the stewards shall contact Racetrack management when weather conditions may become hazardous, and that the stewards shall commence a racing and training delay when weather conditions pose risks to human and equine welfare.

(g) Designation by the Racetrack of an official responsible for enforcing any weather associated training delay.

2165 INFECTIOUS DISEASE MANAGEMENT.

(a) Plans and protocols shall be put in place by each Racetrack to manage an infectious disease outbreak. Such protocols shall be based on guidelines recommended by the AAEP General

Biosecurity Guidelines and AAEP Healthy Horse Protocols: Biosecurity Guidelines for Racetrack Entry and Stabling or more recent versions or developed in consultation with the appropriate State agency or official.

(b) The Regulatory Veterinarian shall maintain written biosecurity guidelines and standard operating procedures and train Racetrack safety personnel in basic biosecurity protocols. All Covered Persons must report any symptoms that may be attributed to an infectious disease to the Regulatory Veterinarian and Safety Director.

(c) During an infectious disease outbreak, the above requirements may be revised as dictated by the circumstances, and all Covered Persons shall adhere to disease control measures implemented by State Racing Commissions or applicable state veterinary authorities.

(d) The Safety Director, or Regulatory Veterinarian if the Safety Director is not a licensed veterinarian, must notify the Chief Veterinarian of the relevant State Department of Agriculture (or comparable state government official) to enable timely and accurate reporting of disease outbreaks at the racetrack to the Equine Disease Communication Center.

2166 HUMAN AMBULANCE SUPPORT.

(a) A Racetrack shall provide a properly staffed and equipped Advanced Life Support ambulance during training and racing hours. If the ambulance is being used to transport an individual, the Racetrack may not conduct a race, or allow Horses with riders on the racetrack, until the ambulance is replaced or available for service.

(b) Racetracks shall ensure the Advanced Life Support ambulance staff has been trained in Concussion management. Any Jockey who falls or is thrown from a Horse during a race must be examined by the Advanced Life Support staff. Advanced Life Support staff shall report their findings to the stewards who will determine if the Jockey may continue riding.

(c) Unless otherwise approved by the State Racing Commission or the stewards, an ambulance shall follow the field at a safe distance during the running of races.

(d) The ambulance must be parked at an entrance to the racing strip except when the ambulance is being used to transport an individual or when it is following the field during the running of a race.

2167 ACCIDENT REPORTING SYSTEM.

(a) Racetracks shall develop standard operating procedures for the collection of data associated with all incidents resulting in Jockey or exercise rider injuries sustained at the racetrack and submit such information to the Authority within ten (10) days of the injury occurrence. Covered Persons involved in, or witnesses to, the circumstances surrounding the injury shall make themselves available to and cooperate with those individuals collecting data for the database.

(b) Data collected shall include:

(01) name of person injured;

(02) nature of the injury;

(03) date and time of day of injury;

(04) occupation of person;

(05) cause of the incident;

(06) weather;

(07) location of the incident; and

(08) witness statements.

2168 EQUINE AMBULANCE.

A dedicated Horse ambulance with personnel trained to operate the ambulance shall at all times be available for rapid deployment during racing and training periods. It is recommended that a second ambulance be available in the case of multiple equine injuries or failure of the primary Horse ambulance.

2169 PADDOCK SAFETY.

Racetracks shall have protocols in place to manage the safety of their saddling paddocks and walking rings. Such protocols should include crowd management policies as well as emergency response procedures for human and equine injuries. An emergency medical technician or paramedic shall be present during saddling.

2170 NECROPSIES.

(a) All Horses that die or are euthanized on Racetrack grounds shall have an autopsy (necropsy) examination performed.

(b) Necropsies should be performed at facilities and by personnel with capabilities and expertise to perform necropsy examination of racehorses. Relationships and contact information shall be included in the necropsy standard operating procedure. The Veterinarian performing the necropsy shall not be an Attending Veterinarian of the affected Horse.

(c) Field necropsy is strongly discouraged. When a field necropsy is the only practical option available, necropsy examinations shall be performed under direct or indirect supervision of a board-certified pathologist including phone call guidance or video conferencing. Necropsies shall be performed in a secure area on all Horses that die or are euthanized on Racetrack premises, isolated from the general public. Whenever possible, the Veterinarian performing the necropsy shall not be an Attending Veterinarian of the affected Horse.

(d) Transportation options for necropsy cases and invoicing for the transportation and necropsy shall be identified prior to need and included in a standard operating procedure. Secure storage, pending transport, and transportation of the body should be managed in such a way that tissue degradation and the development of post-mortem artifacts are minimized. Care shall also be taken to implement sound infection control practices with respect to equine infectious or zoonotic disease.

(e) Gross necropsy examination findings must be submitted by the Regulatory Veterinarian to the Authority within seventy-two (72) hours of receiving the necropsy report, and updates submitted to the Authority within seventy-two (72) hours as the results of ancillary tests and the final report are received. This workflow shall be included in the necropsy standard operating procedures.

2180 SAFETY TRAINING AND CONTINUING EDUCATION.

2181 UNIFORM NATIONAL TRAINERS TEST.

Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall require the use of a uniform National Trainers Test in addition to any State licensing requirements. This test shall have a written component and include practical interviews that demonstrate knowledge and proficiency in basic horsemanship skills, knowledge of racing office protocols, state specific information, and basic equine health care.

2182 CONTINUING EDUCATION.

(a) Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall identify existing, or provide locally, training opportunities for all Racetrack employees having roles in Racetrack safety or direct contact with Covered Horses.

(b) Required annual continuing education shall include:

(01) Regulatory Veterinarians must complete, on an annual basis, at least eight (8) hours continuing education specific to racetrack regulatory medicine;

(02) Attending Veterinarians must complete, on an annual basis, at least eight (8) hours continuing education specifically applicable to racetrack practice;

(03) Medical Directors must complete, on an annual basis, at least eight (8) hours continuing education;

(04) stewards shall be either accredited or actively participating in gaining accreditation through the ROAP and Certification Programs. Maintenance of the ROAP Accreditation requires at least sixteen (16) hours of continuing education every two (2) calendar years.

(05) Trainers must complete, on an annual basis, at least four (4) hours annual continuing education;

(06) assistant trainers must complete, on an annual basis, at least four (4) hours annual continuing education;

(07) Owners must complete, on an annual basis, at least two (2) hours annually;

(08) Racetrack surface managers must complete at least eight (8) hours of continuing education every two (2) years;

(09) Grooms must complete, on an annual basis, at least two (2) hours annual continuing education offered in English and Spanish;

(10) outriders must complete, on an annual basis, at least two (2) hours safety and outrider protocol training delivered locally prior to the beginning of a Race Meet.

(11) Jockeys and exercise riders must complete at least two (2) hours safety and rider protocols delivered locally in English and Spanish prior to the beginning of a Race Meet;

(12) starters and assistant starters must complete, on an annual basis, at least two (2) hours safety training either delivered locally prior to the beginning of a Race Meet or through the ROAP certification; and

(13) Equipment operators must complete, on an annual basis, at least two (2) hours safety training either delivered locally prior to the beginning of a Race Meet or through a continuing education program.

2190 JOCKEY HEALTH.

2191 JOCKEY DRUG AND ALCOHOL TESTING.

Subject to the applicable State Racing Commission electing to enter into an agreement with the Authority, the State Racing Commission shall develop and implement a testing program for drugs and alcohol for Jockeys. The program shall include provisions for medications prescribed by licensed medical doctors that do not affect mental and physical abilities. In the event that a State Racing Commission does not elect to enter into an agreement with the Authority, the Racetracks in such states shall develop and implement a testing program for drugs and alcohol for Jockeys, subject to the approval of the Authority.

2192 CONCUSSION MANAGEMENT.

State Racing Commissions, or Racetracks if the applicable State Racing Commission does not enter into an agreement with the Authority, shall implement a Concussion management program for Jockeys containing the following elements:

(a) Each Jockey shall acknowledge in writing that they have been made aware of the Concussion protocols in place for the facility at which they are riding;

(b) A minimum assessment shall include a current Concussion assessment tool examination;

(c) A return-to-ride guideline shall be established in order to clear a Jockey who has been concussed, or is believed to have been concussed, once the Jockey is declared fit-to-ride; and

(d) The stewards shall be notified when a Jockey is not permitted to ride and when the Jockey has been authorized to return to riding.

2193 INSURANCE.

In states where workers compensation benefits are not afforded to Jockeys by state statute or regulation, Racetracks shall maintain a minimum standard of One Million Dollars ($1,000,000) per incident worth of accident medical expense coverage for all Jockeys.

2200 SPECIFIC RULES AND REQUIREMENTS OF RACETRACK SAFETY PROGRAM.

2210 PURPOSE AND SCOPE.

(a) The purpose of Rule Series 2200 is to establish specific safety rules and requirements designed to enhance equine and Jockey safety in Horse racing.

(b) Violation of, or failure to comply with, the requirements of this Rule 220 Series shall result in disciplinary action by racing officials and the Authority.

(c) Safety rules arising under State laws or regulations not preempted by 15 USC 3054(b) shall be governed by applicable State laws and regulations.

2220 ATTENDING VETERINARIAN.

(a) Only Veterinarians licensed by the State Racing Commission may attend to Covered Horses at any location under the jurisdiction of a State Racing Commission.

(b) Veterinarians attending at any location under the jurisdiction of a State Racing Commission are under the authority of the Regulatory Veterinarian and the stewards.

2221 TREATMENTS BY ATTENDING VETERINARIAN.

The following limitations apply to drug treatments by Attending Veterinarians of Covered Horses that are engaged in activities related to racing, including training:

(a) No drug shall be prescribed, dispensed, or administered except in the context of a valid Veterinarian-client patient relationship between a Veterinarian, the Owner (who may be represented by the Trainer) and the Covered Horse. The Owner is not required to follow the Veterinarian's instructions, but no drug may be administered without a Veterinarian having examined the Horse and provided the treatment recommendation. Such relationship requires the following:

(01) the Veterinarian, with the consent of the Trainer (on behalf of the Owner), has accepted responsibility for making medical judgments about the health of the Horse;

(02) the Veterinarian has sufficient knowledge of the Horse to make a preliminary diagnosis of its medical condition;

(03) the Veterinarian has performed an examination of the Horse and is acquainted with the keeping and care of the Horse;

(04) the Veterinarian is available to evaluate and oversee treatment outcomes, or has made appropriate arrangements for continuing care and treatment;

(05) the relationship is maintained by veterinary visits as needed; and

(06) the medical judgments of the Veterinarian are independent and are not dictated by the Trainer or Owner of the Horse.

(b) The Trainer and Veterinarian are both responsible for ensuring compliance with this Rule, except that the medical judgment to recommend a drug treatment or to prescribe a drug is the responsibility of the Veterinarian, and the decision to proceed with a drug treatment that has been so recommended is the responsibility of the Owner (who may be represented by the Trainer or other agent).

2230 TREATMENT RESTRICTIONS.

(a) Only Trainers or their designees shall be permitted to authorize veterinary medical treatment of Covered Horses under their care, custody, and control at locations under the jurisdiction of the State Racing Commission.

(b) No person other than a Veterinarian licensed to practice veterinary medicine in the State and licensed by the State Racing Commission may prescribe medication with instructions for administration by a Responsible Person for a Covered Horse.

(c) Attending Veterinarians shall not have contact with an entered Horse within twenty-four (24) hours before the scheduled post time of the race in which the Horse is scheduled to compete unless approved by the Regulatory Veterinarian, or an emergency. Any unauthorized contact may result in the Horse being scratched from the race in which it was scheduled to compete and may result in further disciplinary action by the stewards.

(d) The Regulatory Veterinarian may administer emergency treatment to Horses on Racetrack grounds when the Attending Veterinarian is not present.

(e) Except as set forth in paragraph (f) below, no person shall possess a hypodermic needle, syringe capable of accepting a needle or injectable of any kind on racetrack grounds or any facility under the jurisdiction of the Regulatory Authority, unless otherwise approved in writing by the State Racing Commission.

(f) At any location under the jurisdiction of the State Racing Commission, Veterinarians may use only one-time disposable syringes, needles, IV infusion sets; and shall dispose of items in a manner approved by the State Racing Commission and applicable state and governmental regulations.

(g) If a person has a medical condition which makes it necessary to have a syringe at any location under the jurisdiction of the State Racing Commission, that person may request permission of the stewards or the State Racing Commissioning in writing, shall furnish a letter from a licensed physician explaining why it is necessary for the person to possess a syringe, and shall comply with any conditions and restrictions set by the stewards and the State Racing Commission.

2240 VETERINARIANS' LIST.

(a) A Veterinarians' List shall be maintained by the Authority of all Horses that are determined to be ineligible to compete in a Covered Horserace in any jurisdiction until released by a Regulatory Veterinarian.

(b) The following Horses shall be placed on the Veterinarian's List until removed in accordance with Rules 2241 and 2242:

(i) Horses affected by illness, physical distress, medical compromise, unsoundness, injury, infirmity, heat exhaustion, positive test or overage, administration of a medication invoking a mandatory stand down time, administration of Shock Wave Therapy, positive Out-of-Competition test or any other assessment or determination by Regulatory Veterinarians that such Horse is unfit to race.

(ii) Horses which have not started in more than 365 days; and

(iii) Horses which have not made a start prior to January 1 of their 4-year-old year.

(c) Trainers and Owners shall be notified in writing within twenty-four (24) hours that their Horse has been placed on the Veterinarians' List.

(d) Diagnostic testing may be required for any Horse placed on the Veterinarians' List, at the discretion of the Safety Director, Regulatory Veterinarian, or Association Veterinarian.

2241 DURATION OF STAY ON THE VETERINARIANS' LIST.

Horses placed on the Veterinarian's List in accordance with Rule 2240 shall remain on the Veterinarian's List as follows:

(a) Horses placed on the Veterinarians' List for unsoundness or Epistaxis shall remain on the list for fourteen (14) days;

(b) Horses placed on the Veterinarians' List multiple times for unsoundness within the previous 365 days shall remain on the Veterinarians' List for forty-five (45) days for the 2nd time, seventy-five (75) days for the 3rd time, and shall be barred from further racing after the 4th time;

(c) Horses placed on the Veterinarians' List multiple times for Epistaxis within the previous 365 days shall remain on the Veterinarians' List for thirty (30) days for the 2nd time, one-hundred and eighty (180) days for the 3rd time, and shall be barred from further racing after the 4th time;

(d) Horses placed on the Veterinarians' List for illness shall remain on the list for seven (7) days;

(e) Horses treated with Shock Wave Therapy shall be placed on the Veterinarians' List for thirty (30) days; and

(f) If before, during, or after the workout for removal from the Veterinarians' List, the Horse is deemed to be unsound or to have Bled, the stay on the Veterinarians' List shall be extended an additional fourteen (14) days and further diagnostic testing may be required as determined by the Regulatory Veterinarian.

2242 REMOVAL OF HORSES FROM THE VETERINARIANS' LIST.

Regulatory Veterinarians may remove Horses from the Veterinarians' List in accordance with this Rule and shall document such removal to the Authority.

(a) A Horse placed on the Veterinarian's List as unsound or suffering from Epistaxis may be removed from the Veterinarian's List upon satisfaction of paragraphs (1) through (3) below.

(01) A trainer must apply to the Regulatory Veterinarian for permission to work the Horse for removal from Veterinarian's List. Upon receiving such approval, the Trainer and Attending Veterinarian must observe the Horse jog and submit to the Regulatory Veterinarian a co-signed statement that the Horse is fit to perform a Workout.

(02) The Horse must perform a Workout under the supervision of the Regulatory Veterinarian and demonstrate to the satisfaction of the Regulatory Veterinarian that the Horse is sound to race.

(03) The Regulatory Veterinarian determines there is no evidence or signs of Epistaxis, physical distress, medical compromise, unsoundness, or lameness within one (1) hour after the Workout conducted pursuant to paragraph (a)(2) above.

(b) A Horse placed on the Veterinarians' List as physically distressed or medically compromised may be removed from the Veterinarians' List provided sound health has been declared by the Attending Veterinarian or demonstrated to the Regulatory Veterinarian and documented to the Authority.

(c) In addition to the requirements set forth herein and any requirements of the Protocol, if a Horse is placed on the Veterinarians' List for a positive test or overage of a primary substance invoking a mandatory stand down time, a positive Out-of-Competition test, or any other veterinary administrative withdrawal, the Horse shall be prohibited from entering a Race and may be released from the Veterinarians' List only after also undergoing a post-Workout inspection by the Regulatory Veterinarian.

2250 RACEHORSE TREATMENT HISTORY AND RECORDS.

2251 VETERINARY REPORTS.

(a) All Veterinarians shall provide treatment records pursuant to Rules Series 3000. In addition to the uses set forth therein, these records may be used by Regulatory Veterinarians in the performance of their duties at the racetrack, for transfer of sixty (60) day medical records to the new trainer of a claimed Horse, and for purposes of research to enhance the safety and welfare of racehorses.

(b) In addition to the information required to be submitted by Veterinarians pursuant to Rules Series 3000, every Veterinarian who examines or treats a Covered Horse shall, within 24 hours of such examination or treatment, submit the following information in an electronic format designated by the Authority:

(01) the identity of the Horse treated;

(02) the name of the Trainer of the Horse;

(03) the name of the Veterinarian;

(04) contact information for the Veterinarian (phone, email address);

(05) any information concerning the presence of unsoundness and responses to diagnostic tests;

(06) diagnosis;

(07) condition treated;

(08) any medication, drug, substance, or procedure administered or prescribed, including date and time of administration, dose, route of administration (including structure treated if local administration), frequency, and duration (where applicable) of treatment;

(09) any non-surgical procedure performed (including but not limited to diagnostic tests, imaging, and shockwave treatment) including the structures examined/treated and the date and time of the procedure;

(10) any surgical procedure performed including the date and time of the procedure; and

(11) any other information necessary to maintain and improve the health and welfare of the Horse.

2252 RESPONSIBLE PERSONS' RECORDS.

(a) In addition to the information required to be submitted by Responsible Persons under Rule Series 3000, a Responsible Person is responsible for maintaining a record of medical, therapeutic, and surgical treatments and procedures for every Covered Horse in his or her control.

(b) For purposes of this Rule, the term treatment:

(01) means the administration of any medication or substance containing a medication to a Horse by a Responsible Person or his or her designee;

(02) includes the administration of medications that are prescribed by a Veterinarian but administered by the Responsible Person or his or her designee, or medications prescribed or administered by a Veterinarian not licensed by the State Racing Commission; and

(03) specifically excludes medications or procedures directly administered by a Veterinarian licensed by the State Racing Commission or that Veterinarian's employees.

(c) Records must include the information outlined in paragraphs (1) and (2) below.

(01) For medical treatments:

(i) name of the Horse (or, if unnamed, the registered name of the dam and year of foaling);

(ii) name of Trainer;

(iii) generic name of the drug, or brand name if a non-generic drug is used;

(iv) name of the prescribing Veterinarian;

(ix) full name and contact information of the individual that administered the treatment.

(v) date of the treatment;

(vi) route of administration;

(vii) dosage administered;

(viii) approximate time (to the nearest hour) of each treatment; and

(02) For medical procedures, including but not limited to, physiotherapy, acupuncture, chiropractic, and surgeries:

(i) name of the Horse, or, if unnamed, the registered name of the dam and year of foaling;

(ii) name of Trainer;

(iii) diagnosis and condition being treated;

(iv) name of procedure or surgery;

(v) date of the procedure;

(vi) first and last name of the individual that administered or performed the procedure; and

(vii) any other information necessary to maintain and improve the health and welfare of the Horse.

(d) In addition to the uses of records set forth in the Rules Series 3000, records may be used by Regulatory Veterinarians in the performance of their duties at the Racetrack, for transfer of sixty (60) day medical records to the new Owner of a claimed Horse, and for purposes of research to enhance the safety and welfare of racehorses. Records may also be accessed by the State Racing Commission or the stewards.

2253 RECORDS FOR HORSES SHIPPING TO THE RACETRACK.

(a) If a Horse is not stabled at a facility under the Authority's jurisdiction for the full thirty (30) days prior to a Race or Workout for purposes of removal from the Veterinarians' List, the Responsible Person shall obtain and maintain the following information for the previous thirty (30) days:

(01) name of the Horse or, if unnamed, the registered name of the dam and year of foaling;

(02) generic name of the drug, or brand name of the drug if a non-generic drug is used;

(03) date and duration of the treatment;

(04) route of administration;

(05) dosage administered;

(06) surgical procedures;

(07) non-surgical therapies and procedures; and

(08) any other information necessary to maintain and improve the health and welfare of the Horse.

(b) If a Horse is not stabled at a facility under the Authority's jurisdiction for sixty (60) days prior to a Race or Workout for purposes of removal from the Veterinarians' List, the Responsible Person shall obtain and maintain the following information:

(01) the last thirty (30) days of exercise activity at the facility;

(02) the last thirty (30) days of treatments and procedures at the facility; and

(03) any other information necessary to maintain and improve the health and welfare of the Horse.

2260 CLAIMING RACES.

2261 TRANSFER OF CLAIMED HORSE RECORDS.

(a) Entry of Horses subject to being claimed in a Claiming Race implies Owner (Trainer as the agent of the Owner) consent for transfer of all Trainer and veterinary examination and treatment records for the last sixty (60) days to the new Trainer of the claimed Horse.

(b) If a Horse is successfully claimed by a new Trainer, the previous Trainer must transfer Trainer records and authorize transfer of veterinary records to the new Trainer within three (3) days of transfer of the Horse to the new Trainer.

2262 VOID CLAIM.

(a) Title to a Horse which is claimed shall be vested in the successful claimant from the time the field has been dispatched from the starting gate and the Horse becomes a starter.

(b) All claimed Horses shall go to the test barn for observation by the Regulatory Veterinarian.

(c) The claim shall be voided, and ownership of the Horse retained by the original Owner if:

(01) the Horse dies on the racing track;

(02) the Horse is euthanized before leaving the racing track;

(03) the Horse is vanned off of the racing track by discretion of the Regulatory Veterinarian;

(04) the Regulatory Veterinarian determines within one (1) hour of the race that the Horse will be placed on the Veterinarians' List as Bled, physically distressed, medically compromised, unsound, or lame before the Horse is released to the successful claimant; or

(05) the Horse has a positive test for a Prohibited Substance.

(d) The claim shall not be voided if, prior to the Race in which the Horse is claimed, the claimant elects to claim the Horse regardless of whether the Regulatory Veterinarian determines the Horse will be placed on the Veterinarians' List as Bled or unsound or the Horse tests positive for a Prohibited Substance.

2263 WAIVER CLAIMING OPTION.

(a) At time of entry into a Claiming Race an Owner or Trainer may opt to declare a Horse ineligible to be claimed provided:

(01) the Horse has not started in 120 days;

(02) the Horse's last start must have been for a claiming price; and

(03) the Horse is entered for a claiming price equal or greater than the price it last started

for.

2270 PROHIBITED PRACTICES AND REQUIREMENTS FOR SAFETY AND HEALTH OF JOCKEYS.

2271 PROHIBITED PRACTICES.

The following are prohibited practices:

(a) Use of physical or veterinary procedures to mask the effects or signs of injury so as to allow training or racing to the detriment of the Horse's health and welfare.

(b) Use of extracorporeal shock wave therapy in a manner that may desensitize any limb structures during racing or training.

(c) Surgical or chemical neurectomy to cause desensitization of musculoskeletal structures associated with the limbs.

(d) Thermocautery including but not limited to pin firing and freeze firing, or application of any substance to cause vesiculation or blistering of the skin, or a counter-irritant effect.

(e) Use of a device to deliver an electrical shock to the Horse including but not limited to cattle prods and batteries.

(f) Use of electrical medical therapeutic devices including magnetic wave therapy, laser, electro-magnetic blankets, boots, electro-shock, or any other electrical devices that may produce an analgesic effect within forty-eight (48) hours of a training activity or of the start of the published post time for which a Horse is scheduled to race.

2272 SHOCK WAVE THERAPY.

(a) The use of Shock Wave Therapy shall be disclosed to the Regulatory Veterinarian no less than forty-eight (48) hours prior to use and shall not be permitted unless the following conditions are met:

(01) Any Shock Wave Therapy may only be performed with machines that are:

(i) registered and approved for use by the State Racing Commission; and

(iii) used at a previously disclosed location that is approved by the State Racing Commission.

(02) The use of Shock Wave Therapy shall be limited to licensed Veterinarians and must be reported to the Regulatory Veterinarian within forty-eight (48) hours of treatment to the Authority.

(03) Any treated Horse shall be placed on the Veterinarians' List and shall not be permitted to Race or breeze for thirty (30) days following treatment.

(b) The Veterinarian and Trainer shall be suspended from the Racetrack for a period of five (5) days if Shock Wave Therapy has not been reported within forty-eight (48) hours of any treatment or procedure administered to a Covered Horse. For each subsequent omission of reporting, an additional five (5) days suspension shall be added. If there are three (3) violations in a calendar year, the Veterinarian and Trainer shall be suspended for six (6) months in the subsequent calendar year.

2273 OTHER DEVICES.

No electrical or mechanical device or other expedient designed to increase or retard the speed of

Covered Horse, other than the riding crop permitted under these regulations, shall be possessed by anyone, or applied by anyone to a Covered Horse at any time on Racetrack grounds or during a Workout.

2274 OTHER DEVICE PENALTIES.

Penalties for violations of Rule 2273 shall be as follows:

(a) The penalty for a first offense shall be loss of eligibility to obtain a racing license in all racing jurisdictions for ten (10) years.

(b) For any subsequent violation, the penalty shall be loss of eligibility to obtain a racing license in all racing jurisdictions for the life of the Covered Person.

2275 COMMUNICATION DEVICES.

The use of a hand-held communication device by a rider is prohibited while the rider is on the racing track.

2276 HORSESHOES.

(a) Except for full rims 2 mm or less from the ground surface of the Horseshoe, traction devices are prohibited on forelimb and hindlimb Horseshoes during racing and training on dirt or synthetic racing tracks.

(b) Traction devices are prohibited on forelimb and hindlimb Horseshoes during training and racing on the turf.

(c) Traction devices include but are not limited to rims, toe grabs, bends, jar calks and stickers.

2280 USE OF RIDING CROP.

(a) A Jockey or exercise rider who uses a crop during a Race or Workout shall do so only in a professional manner consistent with maintaining focus and concentration of the Horse for safety of Horses and riders, or for encouragement to achieve optimal performance.

(b) A rider may:

(01) Use the crop on the hindquarters to activate and focus the Horse a maximum of six (6) times during a race. The six (6) permitted uses shall be in increments of two (2) or less strikes. The rider must allow at least two (2) strides for the Horse to respond before using the crop again.

(02) Tap the Horse on the shoulder with the crop while both hands are holding on to the reins and both hands are touching the neck of the Horse.

(03) Show or wave the crop to the Horse without physically contacting the Horse.

(04) Use the crop to preserve the safety of Horses and riders.

(c) A rider may not:

(01) Raise the crop with the rider’s wrist above the rider’s helmet when using the crop.

(02) Injure the Horse with the crop or leave any physical marks, such as welts, bruises, lacerations.

(03) Use the crop on any part of the Horse’s body other than the shoulders or hindquarters.

(04) Use the crop during the post parade or after the finish of the race other than to avoid a dangerous situation or preserve the safety of Horses and riders.

(05) Use the crop if the Horse has obtained its maximum placing.

(06) Use the crop persistently even though the Horse is showing no response.

(07) Use a crop on a two (2) year-old Horse in races before April 1st of each year other than to avoid a dangerous situation or preserve the safety of Horses and riders.

(08) Strike another Horse or person with the crop.

(d) In any Race in which a Jockey will ride without a crop that fact shall be declared at entry, included in the official program, and an announcement of that fact shall be made over the public address system.

2281 RIDING CROP SPECIFICATIONS.

(a) Riding crops are subject to inspection by the Safety Officer, stewards, and the clerk of the scales.

(b) All riding crops must be soft-padded.

(c) Riding crops shall have a shaft and a smooth foam cylinder and must conform to the following dimensions and construction:

(01) The maximum allowable weight shall be eight (8) ounces;

(02) The maximum allowable length, including the smooth foam cylinder attachment, shall be thirty (30) inches;

(03) The minimum diameter of the shaft shall be three-eighths of one inch; and

(04) The shaft, beyond the grip, must be smooth, with no protrusions or raised surface, and covered by shock absorbing material that gives a compression factor of at least one millimeter throughout its circumference.

(05) There shall be no binding within seven (7) inches of the end of the shaft.

(06) The smooth foam cylinder is the only allowable attachment to the shaft and must meet the following specifications:

(i) Shall have no reinforcements;

(ii) Shall have a maximum length beyond the shaft of one inch;

(iii) Shall have a minimum diameter of 0.8 inches and a maximum width of 1.6 inches;

(iv) There shall be no other reinforcements or additions beyond the end of the shaft;

(v) Shall be made of shock absorbing material with a compression factor of at least five millimeters throughout its circumference;

(vi) Shall be made of a waterproof, ultraviolet, and chemical resistant foam material that is durable and preserves its shock absorption in use under all conditions; and

(vii) Shall be replaced after reasonable wear and tear is visibly evident.

(07) Riding crops shall not be altered and shall have an appropriate label or marking designating that the riding crop meets the required standards as established by the Authority

2282 RIDING CROP VIOLATIONS AND PENALTIES.

(a) Violations of Rule 2280 shall be categorized as follows, with the exception that use of the crop for the safety of Horse and rider shall not count towards the total crop uses:

(01) Class 3 Violation – one (1) to three (3) strikes over the limit.

(02) Class 2 Violation – four (4) to nine (9) strikes over the limit.

(03) Class 1 Violation – ten (10) or more strikes over the limit.

(b) Unless the stewards determine the merits of an individual case warrant consideration of an aggravating or mitigating factor, the penalties for violations are as follows:

(01) Class 3 Violation –

(i) $250 or 10% of Jockey's portion of the purse, whichever is greater;

(ii) Minimum 1-day suspension for the Jockey; and

(iii) 3 points;

(02) Class 2 Violation –

(i) $500 or 20% of Jockey's portion of the purse, whichever is greater;

(ii) Horse disqualified from purse earnings,

(iii) Minimum 3-day suspension for the Jockey; and

(iv) 5 points;

(03) Class 1 Violation –

(i) $750 fine or 30% of Jockey's portion of the purse, whichever is greater,

(ii) Horse disqualified from purse earnings,

(iii) Minimum 5-day suspension for the Jockey;

(iv) 10 points.

2283 MULTIPLE VIOLATIONS.

(a) Stewards shall submit violations of Rule 2282 to the Authority to identify when multiple violations warrant additional suspensions consistent with the following schedule:

(01) 11- 15 points – 7 days;

(02) 16-20 points – 15 days; and

(03) 21 or more points – 30 days.

(b) Points assigned under Rule 2282 shall expire according to the following schedule:

(01) Class 3 Violation - 6 months;

(02) Class 2 Violation – 9 months; and

(03) Class 1 Violation - 1 year.

(c) For purposes of paragraph (b), points are expunged from the date of final adjudication of the violation and not from the date of the violation. Mandatory suspensions are based on points

accumulated for multiple violations and do not apply to single violations.

2290 REQUIREMENTS FOR SAFETY AND HEALTH OF JOCKEYS.

2291 JOCKEY ELIGIBILITY.

(a) A Jockey shall pass a physical examination given within the previous twelve (12) months by a licensed physician affirming the Jockey's fitness to participate as a Jockey, as well as a baseline Concussion test using a current Concussion testing protocol. The results of the physical examination and the baseline Concussion test shall be submitted to the State Racing Commission and the Authority.

(b) The stewards may require that any Jockey be reexamined and may refuse to allow any Jockey to ride in a race or Workout pending completion of such examination.

2292 JOCKEY AND EXERCISE RIDER MEDICAL HISTORY INFORMATION.

(a) At all times while mounted on a Horse at a Racetrack, a Jockey or exercise rider shall securely attach to his or her safety vest one or more medical information cards describing his or her medical history and any conditions pertinent to emergent care, including a listing of any previous injuries, drug allergies and current medications.

(b) The stewards shall confirm compliance during their safety vest inspections at the beginning of the season and with random inspections throughout the Race Meet.

(c) The stewards may, in their discretion, take disciplinary action against, suspend, make ineligible to race, or fine any Jockey or exercise rider found in violation of this Rule.

2293 EQUIPMENT.

(a) Helmets.

(01) Any person mounted on a Horse or stable pony anywhere on racetrack grounds shall wear a properly secured safety helmet at all times.

(02) All starting gate personnel shall wear a properly secured safety helmet at all times while performing their duties or handling a Horse.

(03) The safety helmet may not be altered in any manner and the product marking shall not be removed or defaced.

(04) The stewards, or their designee, shall inspect safety helmets at the beginning of a Race Meet and randomly throughout the Race Meet.

(05) The Clerk of Scales shall report to the stewards any variances of safety helmets seen during the course of their work.

(06) The helmet must comply with one of the following minimum safety standards or later revisions:

(i) American Society for Testing and Materials (ASTM 1163);

(ii) European Standards (EN-1384 or PAS-015 or VG1);

(iii) Australian/New Zealand Standards (AS/NZ 3838 or ARB HS 2012); or

(iv) Snell Equestrian Standard 2001.

(b) Vests.

(01) Any person mounted on a Horse or stable pony on the racetrack grounds must wear a properly secured safety vest at all times.

(02) All starting gate personnel must wear a properly secured safety vest at all times while performing their duties or handling a Horse.

(03) The safety vest may not be altered in any manner and the product marking shall not be removed or defaced.

(04) The stewards shall inspect safety vests at the beginning of a Race Meet and randomly throughout the Race Meet.

(05) The clerk of scales shall report to the stewards any variances of safety vests seen during their course of work.

(06) The safety vest must comply with one of the following minimum standards, as the same may be from time to time amended or revised:

(i) British Equestrian Trade Association (BETA):2000 Level 1;

(ii) iEuro Norm (EN) 13158:2000 Level 1;

(iii) American Society for Testing and Materials (ASTM) F1781-08 or F1937;

(iv) Shoe and Allied Trade Research Association (SATRA) Jockey Vest Document M6-3; or

(v) Australian Racing Board (ARB) Standard 1.1998.

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.

End Notes

1. Comment to Article 2.3.2: This Article does not apply to a Covered Horse that does not provide a urine Sample due to the lack of need to urinate. Any challenge based on Intractability will be adjudicated in accordance with the procedures for Minor Infractions.

2. Comment to Article 4.2.1: Additional guidance on the use of therapeutic substances is available through the Agency's website.

3. Any challenge to a sit out period based on Article 5.4 will be adjudicated in accordance with the procedures for Minor Infractions

4. If a deadline set forth in the Protocol falls on a weekend or federal holiday, the deadline will be the next business day

5. Comment to Article 10.5: This Article will only apply in truly exceptional circumstances, for example, where a Covered Person could prove that, despite all due care, they or their Covered Horse were sabotaged by a competitor or a Covered Horse ingested feed contaminated at the time of manufacture, growth, or harvest. Conversely, No Fault or Negligence would not apply, for example, in the following circumstances: (a) a positive test resulting from a mislabeled or contaminated supplement; (b) the Administration of a Prohibited Substance by someone employed, supervised, or contracted, or requested by any Covered Person associated with the Covered Horse to provide care, training, or other services to a Covered Horse; and (c) sabotage or contamination of the Covered Horse's food or drink by a Covered Person associated with the Covered Horse.

6. Comment to Article 10.12.1: The Agency expect that State Racing Commission will determine the impact a period of Ineligibility has on a license to ensure compliance with the Protocol

7. Comment to Article 10.12.1.1: The Responsible Person, or Owner if no Responsible Person, has three business days to arrange for the Covered Horse to leave the Racetrack

Exhibit

G

Statement from USADA CEO Travis T. Tygart on Equine Anti-Doping and Medication Control Program Negotiations

Statement / December 23, 2021

"We are deeply disappointed to announce that we have been unable to reach an agreement with the Horseracing Integrity and Safety Authority for USADA to become the enforcement agency for the anti-doping and medication control program for thoroughbred racing under the Horseracing Integrity and Safety Act. After months of negotiations, we have been unable to enter an agreement in line with the requirements of the Act, and one which would have given us a reasonable chance to put in place a credible and effective program. While we are obviously saddened by the outcome at this stage, we tried our absolute best to find a way forward but without success."

"While we desperately tried to reach an agreement to implement the program, without compromising our values, we have always said the passing of the legislation and the finalization of uniform, robust rules are huge victories for the horses and the equine industry. We are honored to have been involved with these efforts to restore the integrity of thoroughbred horse racing. Though we are unsure what the future holds for USADA – if any – in this effort, we have offered to assist the Authority and others in the industry to ensure that the sport gets the program it needs and that the horses deserve."

Exhibit

H

HORSERACING INTEGRITY AND SAFETY AUTHORITY

Horseracing Integrity and Safety Authority Appoints Lisa Lazarus as Chief Executive Officer

Lazarus, Partner and Head of the Equestrian Practice at Morgan Sports Law, to assume leadership of the Authority in February

January 11, 2022 – The Horseracing Integrity and Safety Authority (HISA) Board of Directors announced today that Lisa Lazarus will serve as Chief Executive Officer of the Authority starting February 15, 2022. The board reached this decision after engaging Russell Reynolds to undertake a nationwide search for a permanent Chief Executive Officer. Under Lazarus' leadership, HISA will implement the racetrack safety program on July 1, 2022, engage a best-in-class independent enforcement agency to oversee the Authority's Anti-Doping and Medication Control (ADMC) program, and work with stakeholders across the U.S. to evaluate and improve both programs on an ongoing basis.

"We are thrilled to have Lisa on board as we approach HISA's program effective date in six short months" said Charles Scheeler, Chairman of the Board of Directors. "Her deep background in sports business and law will be on full display as she leads the racing industry into a new, safer era of clean competition under uniform rules and regulations."

"I look forward to working with the impressive and diverse array of independent and industry experts at HISA to make racing safer and fairer for all. As someone who has worked with the industry over the course of my career, and as a horse lover, I'm honored to be taking on this role," said Lazarus.

Lazarus established and leads the Equestrian Practice at Morgan Sports Law, where she provides counsel on health and safety issues and rule compliance in addition to representing athletes, owners and trainers in disputes before national and international governing bodies. Prior to joining Morgan Sports Law, she served as General Counsel and later Chief of Business Development & Strategy at the Fédération Equestre Internationale, the international governing body for equestrian sports. Prior to her focus on the equine sporting industry, Lazarus spent a decade at the National Football League where she served as the league's Labor Relations Counsel, representing the NFL's 32-member clubs in collective bargaining issues and

HORSERACING INTEGRITY AND SAFETY AUTHORITY

in contested arbitrations, including anti-doping enforcement matters. She then became Senior Legal Counsel before taking the role of Senior Director of Partner Development for NFL International at their headquarters in London, England. Lazarus began her legal career working as an associate at Akin Gump for four years after graduating from Fordham University School of Law and clerking for a Federal District Court Judge in Memphis, Tennessee.

Under the leadership of Interim Chief Executive Officer Hank Zeitlin, the Authority's advisory committees drafted proposed rules and regulations and sought industry feedback through an extensive stakeholder engagement process, resulting in the successful submission of the Racetrack Safety Program to the Federal Trade Commission on December 6. The ADMC Committee worked with USADA to release six documents for public input, including the proposed Equine Protocol, Prohibited List, Definitions, Equine Arbitration Procedures, Testing and Investigation Standards, and Standards for Laboratories and Accreditation.

"The significant progress achieved in just a short period of time is a testament to Hank's professionalism and intimate knowledge of the racing industry. He convened a small yet highly capable staff to undertake this enormous effort with the advisory committees, and the work products speak for themselves," said Scheeler. "The Board of Directors deeply appreciate Hank's leadership and service to the racing community."

"Being a part of the process to improve and modernize the sport has been a privilege," said Zeitlin. "I look forward to working with Lisa in the coming months as my time at HISA comes to a close. There is no doubt in my mind that the Authority is in good hands as it continues its mission to protect the athletes, both equine and human, and the integrity of the sport."