FEDERAL TRADE COMMISSION

[Matter No. P222100]

HISA Anti-Doping and Medication Control Rule

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 Anti-Doping and Medication Control on August 17, 2022 and supplemented on October 13, 2022. 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 become effective January 1, 2023. Comments must be received on or before November 14, 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 Anti-Doping and Medication Control'' on your comment and file your comment online at *https://www.regulations.gov.* 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.

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]

Pursuant to Section 3053(a) of the Horseracing Integrity and Safety Act of 2020 and Commission Rule 1.142, notice is hereby given that, on August 17, 2022, and as supplemented on October 13, 2022, the Horseracing Integrity and Safety Authority (''HISA'' or the ''Authority'') filed with the Federal Trade Commission a proposed Anti-Doping and Medication Control rule and supporting documentation as described in Items I, II, III, IV, and IX below, which Items have been prepared by HISA. The Office of the Secretary of the Commission determined that the filing complied with the Commission's rule governing such submissions.[5] The Commission publishes this document to solicit comments on the proposed rule from interested persons.

[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 through 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).

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

a. Background and Purpose

The Act recognizes that the establishment of a national set of uniform standards for racetrack safety and medication control will enhance the safety and integrity of horseracing. As part of this endeavor, section 3053(a) of the Act directs the Authority to develop proposed rules relating to ''(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; [. . .] (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; and (10) a process or procedures for disciplinary hearings.'' [6]

With the review, input, and ultimate approval of the Anti-Doping and Medication Control Standing Committee (''ADMC'') and the Authority's Board of Directors, the proposed rules: (1) set forth a list of anti-doping and controlled medication rules; (2) set forth a list of prohibited substances and methods; (3) set forth a framework for the testing of covered horses and the investigation of possible rule violations by the Horseracing Integrity and Welfare Unit (the ''Agency''); (4) set forth a framework by which laboratories will be accredited and will analyze samples for prohibited substances and markers of prohibited methods; (5) specify the civil sanctions that apply to anti-doping and controlled medication violations; (6) create procedures for disciplinary hearings, tailored to the nature of the charge. The Agency participated in the development of the proposed rule and approves of the rules as filed.

In compliance with 16 CFR 1.142(a), the Authority states that the reason for adopting the Protocol is that the Horseracing Integrity and Safety Act of 2020 (''Act'') mandates and empowers the Horseracing Integrity and Safety Authority (the ''Authority'') to establish a uniform anti-doping and controlled medication program to improve the integrity and safety of horseracing in the United States (''Program''). The Equine Anti-Doping and Controlled Medication Protocol (''Protocol'') has been developed and issued by the Authority as part of that mandate. It contains or incorporates by reference rules,

[6] 15 U.S.C. 3053(a)(2)–(3), (8)–(10).

standards, and procedures to improve and protect the integrity and safety of horseracing in the United States by deterring and penalizing the improper administration or application of Prohibited Substances and Prohibited Methods to Covered Horses. The Protocol is split into five chapters: (1) the purpose, scope, and organization of the Protocol; (2) the Prohibited List, rules of proof, and testing and investigations; (3) the Equine Anti-Doping Rules; (4) the Equine Controlled Medication Rules; and (5) other violations and general procedure/administration.

The Protocol has intentionally divided the regulation of Anti-Doping Rule Violations and Controlled Medication Rule Violations into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other. Anti-Doping Rule Violations involve Banned Substances or Banned Methods, which are substances/methods that should never be in a horse's system or used on a horse as they serve no legitimate treatment purpose. Conversely, Controlled Medication Rule Violations involve Controlled Medication Substances or Controlled Medication Methods, which are substances/methods that have been determined to have appropriate and therapeutic purposes, and so may be used outside the Race Period, except if specified otherwise.

The Protocol and related rules are intended to address the need for uniformity in horseracing, to protect the welfare of Covered Horses, to safeguard the integrity of horseracing, and to ensure the confidence of stakeholders (including the betting public) in the sport. Prior to the implementation of the Authority, horseracing has been regulated in the United States by the States. By its nature, this results in a lack of uniformity in the rules of horseracing, including in many vital areas of equine safety and the proper regulation of the use of prohibited substances. Congress acted to impose a comprehensive program that would effectively regulate horseracing with a common set of rules. The Protocol was developed in collaboration with industry experts and stakeholders who brought to the endeavor an unparalleled depth of equine safety, anti-doping, veterinary medicine, sports integrity, and compliance experience. The Protocol will provide one standard set of rules that apply to doping and medication control, laboratory drug testing methods and techniques, sample collection procedures, investigatory procedures, and hearing and adjudication procedures that will enhance the effective regulation of horse safety and medication issues.

In considering reasonable alternatives to the proposed rule or modification that may accomplish the stated objective, it is important to underline that the Authority and the development of the Protocol is unprecedented. As a consequence, there are of course countless ''alternatives'' on various issues, but the Authority has sought to combine the best practice elements from various sources, including rules and practices developed by the global anti-doping community, horseracing authorities (national and international), and other equine sport organizations.

The Protocol will affect Covered Persons, Covered Horses, and Covered Horseraces by ensuring that horseracing is conducted in a manner that is consistent with the highest standards of integrity and that prioritizes the safety of Covered Horses and Covered Persons. The welfare of Covered Horses is secured by rules that strictly ban and penalize the use of doping substances and methods, and that sanction the misuse of therapeutic medications. All Covered Persons are required to comply with the Protocol and related rules, and to cooperate with the Authority and the Agency in relation to all aspects of doping and medication control, including sample collection, testing, and investigation procedures. The manner in which the Protocol implements these requirements is outlined in detail in Item II of this Document.

In developing the Protocol and related rules in a manner that is consistent with the Act and the rules and regulations applicable to the Authority, the Authority took the following principles and mandates into consideration, as directed by section 3055(b) of the Act:

(1) Covered Horses should compete only when they are free from the influence of medications, other foreign substances, and methods that affect their performance. The entire Protocol is dedicated to this principle, and the elaborate anti-doping and controlled medication rules work toward the objective of ensuring that Covered Horses compete in a manner that is free of the influence of doping substances, medications, and methods that affect their performance. The Prohibited List and related Technical Document prescribe the substances and methods that are prohibited and permitted under certain circumstances. The Standards (Rules 5000 and 6000 Series) set out comprehensive investigatory and sample collection provisions and an accreditation system that ensures accurate laboratory testing, and the Arbitration Procedures establish a set of disciplinary procedures to deal fairly but firmly with violations of the rules.

(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. In the Protocol, Rule 3111 operates together with the Prohibited List to ban substances and methods for which there exists medical, veterinary, or other scientific evidence or experience to a support their actual or potential masking properties (''Banned Substances'' and ''Banned Methods'') and to restrict the use of medications during the Race Period (''Controlled Medication Substances'' and ''Controlled Medication Methods''). Certain Controlled Medication Substances are also prohibited during workouts, as set out in the Prohibited List. The Protocol also operates in conjunction with the Rule 2000 Racetrack Safety Program, which sets forth stringent rules for placing Covered Horses on the Veterinarians' List and requires the Regulatory Veterinarian to oversee removal from the list. These processes help to ensure that injured and unsound horses do not train or participate in Covered Horseraces. It should also be noted that Rule 2271 in the Racetrack Safety Program prohibits the ''[u]se 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.''

(3) Rules, standards, procedures, and protocols regulating medication and treatment methods for Covered Horses and Covered Horseraces should be uniform and uniformly administered nationally. The Protocol preempts state laws and provides instead a uniform set of comprehensive rules that embrace all of the areas previously addressed in state anti-doping and medication control regulation schemes. The entire scheme will be administered nationally by the Authority and the Agency to ensure uniform and consistent application of the law. The Protocol and related rules will create a comprehensive program that is unprecedented in horseracing as previously conducted and regulated in the United States.

(4) Consideration should be given to international anti-doping and medication control standards of the International Federation of Horseracing Authorities (''IFHA'') and the Principles of Veterinary Medical Ethics of the

American Veterinary Medical Association. As directed by the Act, the ADMC has scrutinized the IFHA standards and rules very closely and also considered the Principles of Veterinary Medical Ethics of the American Veterinary Medical Association in preparing the Protocol. The World Anti-Doping Code also provided much of the inspiration for the Protocol, adapted as necessary for horseracing, taking into account national and international horseracing rules and Equine Anti-Doping and Controlled Medication Regulations of the International Equestrian Federation (*i.e.,* the global governing body for equestrian sport).

(5) The administration of medications and treatment methods to Covered Horses should be based upon an examination and diagnosis that identifies an issue requiring treatment for which the medication or method represents an appropriate component of treatment. The Protocol addresses the requirement for a sound diagnosis as a prerequisite for treatment and the need for such treatment not to be administered in a manner contrary to horse welfare. Specifically, Rule 3040(b)(3) states that it is the personal responsibility of each Responsible Person to ensure that treatments and medications administered to his or her Covered Horses (i) are administered only on the advice of a Veterinarian or (if a prescription is not required) following sufficient due diligence regarding the treatment or medication; (ii) are not administered in a manner detrimental or contrary to horse welfare; (iii) are the minimum necessary to address the diagnosed health concerns identified during the veterinary examination and diagnostic process; (iv) do not contain a Banned Substance or involve a Banned Method; and (v) do not otherwise violate the Protocol. Further, Rule 3314 penalizes use of a Controlled Medication Substance or Method in a manner that is contrary to horse welfare. In particular, Rule 3314(a) specifically mandates that any use of a Controlled Medication Substance or a Controlled Medication Method on a Covered Horse must ''(i) be justified by the Covered Horse's medical condition(s) as diagnosed by a Veterinarian, (ii) have been recommended by a Veterinarian in the context of a valid veterinarian-patient-client relationship, (iii) go no further than the minimum necessary to address the diagnosed health concerns, and (iv) be in the best interests of the Covered Horse's health and welfare.'' Rule 3314(b) also states that it is ''the personal and non-delegable duty of the Responsible Person'' to ensure the above requirements in Rule 3314(a) are complied with. The Protocol also establishes in Rules 3227 and 3327 that an aggravating circumstance that may be taken into account in assessing sanctions for a rule violation may include ''administration of a Controlled Medication Substance that is detrimental to the health and welfare of the horse or is designed to deceive the betting public.'' It should also be noted that Rule 2221 (of the previously approved Racetrack Safety Rule) also establishes examination and diagnoses requirements in the context of the veterinarian-client-patient relationship.

(6) The amount of therapeutic medication that a Covered Horse receives should be the minimum necessary to address the diagnosed health concerns identified during the examination and diagnostic process. As noted above, Rule 3040(b)(3) and Rule 3314 specifically address the requirement that any use of a Controlled Medication Substance or a Controlled Medication Method on a Covered Horse must go no further than ''the minimum necessary to address the diagnosed health concerns.''

(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. The Protocol addresses this issue in several ways. It requires all Covered Persons to cooperate promptly and completely with the Authority and the Agency in the exercise of their respective powers under the Act and the Protocol and related rules (Rule 3040(a)). Each Responsible Persons is required to maintain accurate, complete, and up-to-date treatment records of his or her Covered Horses in a form specified by the Agency, and to provide the records on request to the Agency (Rule 3040(b)(8)). Responsible Persons must declare to the Agency any use of Banned Substances or Banned Methods on a horse prior to it becoming a Covered Horse (Rule 3040(b)(9)). To facilitate out-of-competition testing, Responsible Persons must file whereabouts information if their Covered Horses are moved to a private facility (Rule 3040(b)(10)). Attending Veterinarians must keep updated treatment records in an electronic database designated by the Agency or in any other form designated by the Agency and must provide access on request to copies of these records (Rule 3040(d)). Refusal or failure to cooperate with the Authority or the Agency, or the commission of a Whereabouts Failure, constitutes a violation of the Protocol under Rule 3510. Several provisions in the Rule 2000 Series complement the Protocol's disclosure requirements. Rule 2551, for example, requires every Veterinarian who examines or treats a Covered Horse to submit to the Authority, within 24 hours of such examination or treatment medications, treatment records with details as prescribed in the Rule.

In further compliance with the Act, the Protocol establishes a comprehensive set of violations and hearing procedures to prohibit certain conduct, to provide a process for determining the existence of a violation; of charging a Covered Person with a violation; and with resolving the matter in a full and fair hearing process. The Protocol authorizes the imposition of sanctions that comport with the severity of the violation. Consistent with 15 U.S.C. 3057(d)(2), the violation and sanction system is tailored to the unique aspects of horseracing in that it has the power to declare a Covered Person or Covered Horse ineligible to race for a specified time, imposes substantial fines upon Covered Persons, and establishes a points system to implement a system of penalties for multiple violations of the Protocol. These penalties are common in the adjudication and sanction of violations in the world of horseracing. The sanctions also include forfeiture of purse, disqualification of horses, and changes to the order of finish in horse races. The elaborate hearing procedures and penalty rules ensure that violations are consistently and fairly penalized, which in turn deters future violations, and maintains the integrity and conduct of fair and transparent horseraces. Effective sample collection and testing techniques, as set forth in Rule Series 5000 and 6000 also serve to enhance successful prosecution of violations, which deter future violations. The goal of transparency is also served by operation of the public disclosure rules in the Protocol, which mandate that the public be informed of information concerning specific cases as the cases are adjudicated or otherwise resolved.

The components of the Protocol and related rules comport with the baseline standards in 15 U.S.C. 3055(g)(2)(a), which 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). Any deviations from the baseline standards have been approved by the Authority and the Agency following detailed consideration and adoption of an approach that is either stricter or more consistent with horseracing.

[Technical document insert]

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 Registration Proposed Rule and Discussion of Alternatives

a. Existing Standards

Anti-doping and controlled medication rules currently vary from State to State, but the overall structure of the rules governing horseracing is generally consistent among the States. In particular, the rules of horseracing center around a number of common subject areas, including the licensing of racing associations and of individual participants in horseracing, medication control rules, pari-mutuel wagering rules, the operation of various incentive funds, rules concerning the running of the race, and rules establishing disciplinary measures and hearing procedures. The basic precepts of many of the rules pertaining to violations, sanctions, hearing procedures, and investigatory powers have been in force in racing states for many years, and the Authority has reviewed and considered key provisions from numerous states in developing these rules.

The Association of Racing Commissioners International (''ARCI'') sets forth standards and protocols in its Model Rules of Racing (''ARCI Rules''). Relying upon the collective expertise of regulatory personnel in member jurisdictions in consultation with regulated entities, industry stakeholders, and individuals, ARCI committees regularly consider ways to improve and enhance the regulation of racing. The Authority considered the ARCI Model Rules of Racing when developing the Protocol and related rules. Likewise, the Authority considered rules from other racing jurisdictions such as the British Horseracing Authority's Rules of Racing.

The Authority also considered and relied heavily on international anti-doping standards, including the World Anti-Doping Code (applicable to human athletes) and the International Equestrian Federation (''FEI'') Equine Anti-Doping and Controlled Medication Regulations (applicable at the international level to various equestrian disciplines). Those regulations provide a robust anti-doping framework that has been tested before arbitration tribunals for many years, and that has generated a well-developed body of precedent and guidance for interpreting the provisions in those frameworks.

The Authority, in consultation with the ADMC and the Agency, reviewed these existing standards and tailored them to the Authority's regulatory structure and goals, and to the specificities of horseracing.

The provisions of these Series were made publicly available on the Authority website at *www.hisaus.org/regulations* on June 1, 2022. A number of stakeholder comments were received, which are addressed further in Item III below. Additionally, the Authority consulted directly with a number of industry officials and participants in obtaining feedback on the proposed Rules. The Authority is submitting those comments along with this Notice of Filing as Exhibit A, which is available for public inspection at the corresponding docket at *https://www.regulations.gov*. Furthermore, all the important source materials on which the Authority relied in developing its proposed rule are also collected at that docket as Exhibit B.

b. Terms of Substance: Rule Series 3000—Equine Anti-Doping and Controlled Medication Protocol

1. Purpose, Scope, and Organization—Rules 3010–3090

Chapter I of the Protocol has been developed taking account of the requirements of the Act, including, in particular, those set out at sections 3054 and 3055 of the Act.

With the approval of the Commission, the Protocol will go into effect on January 1, 2023. It contains or incorporates by reference rules, standards, and procedures to improve and protect the integrity and safety of horseracing in the United States by deterring and penalizing the improper administration or application of Prohibited Substances and Prohibited Methods to Covered Horses. The Protocol is divided into five substantive chapters: (1) the purpose, scope, and organization of the Protocol; (2) the Prohibited List, rules of proof, and testing and investigations; (3) the Equine Anti-Doping Rules; (4) the Equine Controlled Medication Rules; and (5) other violations and general procedure/administration.

The Protocol has intentionally divided the regulation of Anti-Doping Rule Violations and Controlled Medication Rule Violations into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other. Anti-Doping Rule Violations involve Banned Substances or Banned Methods, which are substances/methods that should never be in a horse's system or used on a horse as they serve no legitimate treatment purpose. Conversely, Controlled Medication Rule Violations involve Controlled Medication Substances or Controlled Medication Methods, which are substances/methods that have been determined to have appropriate and therapeutic purposes, and so may be used outside the Race Period, except if specified otherwise. This division accords with international best practices. However, the two distinct processes share many common features and rules, and therefore the Protocol is streamlined to make the processes consistent with each other wherever possible.

The Protocol will be implemented and enforced on behalf of the Authority by the Agency, which has created an entity designated as the Horseracing Integrity and Welfare Unit (''Agency''). In addition, and only where so agreed, State Racing Commissions acting under the delegated authority of the Authority or the Agency (Rule 3010(e)) may also assist in implementation.

In accordance with section 3055(a)(1) of the Act, the Protocol applies to all Covered Horses, Covered Persons, and Covered Horseraces (Rule 3020). Pursuant to section 3054 of the Act, Covered Persons must register with the Authority.

In developing the Protocol, the Authority reviewed and considered various anti-doping and controlled medication rules, including:

Exhibit B.2. ARCI Model Rules of Racing, including, in particular, the penalty provisions and rules on multiple medication violation.

Exhibit B.3. FEI Equine Anti-Doping & Controlled Medication Regulations.

Exhibit B.4. FEI Atypical Findings Policy.

Exhibit B.5. World Anti-Doping Code.

Exhibit B.6. British Horseracing Authority Equine Anti-Doping Rules.

2. Prohibited List, Rules of Proof, and Testing and Investigations—Rules 3110–3140

The Protocol incorporates the Prohibited List, which identifies the Banned Substances and Banned Methods that are prohibited at all times on the basis of the Agency's determination that medical, veterinary, or other scientific evidence or experience supports their actual or potential (i) ability to enhance the performance in Covered Horses, (ii) masking properties, or (iii) detrimental impact on horse welfare. The Prohibited List also identifies Controlled Medication Substances and Controlled Medication Methods, which are prohibited for Use on or Administration to a Covered Horse during the Race Period and must not be present in a Post-Race Sample or Post-Work Sample, except as specified otherwise. In other words, the phrase ''Prohibited Substances and Prohibited Methods'' refers to Banned Substances and Banned Methods as well as Controlled Substances and Controlled Medication Methods that are only restricted during the Race Period. The Prohibited List will be published at least annually (Rule 3112).

The Prohibited List is supplemented by the ''Technical Document—Prohibited Substances,'' which enumerates the Prohibited Substances that fall into the general categories listed in the Prohibited List and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical document also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and that are, therefore, subject to more flexible sanctions.

In disciplinary cases brought under the Protocol, the Agency will have the burden of establishing that a violation of the Protocol has occurred to the comfortable satisfaction of the hearing panel, bearing in mind the seriousness of the allegation made (Rule 3121), and facts may be established by any reliable means (Rule 3122). The ''comfortable satisfaction'' standard of proof is greater than a mere balance of probability (*i.e.,* a preponderance of the evidence) but less than clear and convincing evidence or proof beyond a reasonable doubt (Rule 3121).

Only the Agency (and those authorized by the Agency) may initiate and direct testing on any Covered Horse. The Agency will have broad authority to conduct testing both in and out of competition (Rule 3132), and samples collected will be owned by the Authority (Rule 3135). Samples obtained from Covered Horses will be analyzed primarily to detect the presence of Prohibited Substances (Rule 3137).

State Racing Commissions, Racetracks, Race Organizers, and Training Facilities shall not initiate or direct any Testing of Covered Horses. However, they may request that the Agency initiate and direct enhanced or additional Testing (*e.g.,* in relation to a particular Covered Horserace). The Agency may accept or decline such request at its absolute discretion. Where the Agency accepts the request, the costs of Sample collection and analysis shall be borne by the entity requesting the additional or enhanced Testing. The Agency may conduct the Testing itself or delegate the Testing to the relevant State Racing Commission. (Rule 3132).

3. Equine Anti-Doping Rules—Rules 3210–3260

The Equine Anti-Doping Rules set out in Chapter III of the Protocol apply to conduct involving Banned Substances or Banned Methods, *i.e.,* substances and methods prohibited at all times. The violations set out in this Chapter are included as directed by section 3057(a)(2) of the Act, and are also substantively modelled on World Anti-Doping Code violations. The violations prohibit use, possession, trafficking, and administration to a Covered Horse of Banned Substances or Banned Methods (Rules 3213 and 3214). It is a violation to evade, refuse or fail to submit a Covered Horse to sample collection (Rule 3215), and the presence of a Banned Substance in a sample collected from a Covered Horse is also a violation (Rule 3212). In accordance with section 3057(a)(2) of the Act, presence and use violations are strict liability offenses for the Responsible Person, although other Covered Persons may also be liable to the same extent if they are complicit in the violation. Other prohibited conduct includes tampering with doping control, complicity with another person's violation, associating with a person who is banned, and improper retaliation against actual or potential whistle-blowers or intimidation of witnesses (Rule 3216). Attempts to commit Anti-Doping Rule Violations are also sanctionable.

As directed by the Act, the Authority has developed a list of civil sanctions for Anti-Doping Rule Violations. The Protocol and Prohibited List establish uniform rules imposing civil sanctions against Covered Persons and Covered Horses for Anti-Doping Rule Violations (and also for Controlled Medication Rule Violations, addressed under chapter IV of the Protocol), as directed by section 3057(d) of the Act. The range of civil sanctions (a) take into account the unique aspects of horseracing; (b) are designed to ensure fair and transparent Covered Horseraces; and (c) are intended to deter violations. The severity of the sanctions depends on the nature of the violation, and allows an opportunity for adjustment in penalty depending on the violation and facts involved.

A mandatory part of each sanction will include Public Disclosure of relevant information, including the Covered Person's name, the violation, and consequences imposed (Rules 3231 and 3620).

If the violation arises from a Post-Race Sample or occurs during the Race Period, the Covered Horse's results at that Covered Horserace will automatically be disqualified, because the horse competed with a Banned Substance in its system, irrespective of the reason why the Banned Substance was there or any degree of fault on the part of the Covered Person (Rule 3221(a)). Subsequent results may also be disqualified (Rule 3221(b)) and in any case of disqualification, all purses and other compensation, prizes, trophies, points, and rankings are forfeited and must be repaid or surrendered to the race organizer, and the results of the other Covered Horses in the race in question must be adjusted accordingly (Rule 3221(c)).

The Protocol now also specifies what happens to the race classification pending the outcome of the disciplinary proceedings (Rules 3221 and 3321). Further, Rule 3221(a) allows for the Agency, the Responsible Person, and the Owner of the Covered Horse in question to agree (or to ask the Arbitral) to apply Rule 3221 immediately, *i.e.,* prior to adjudication of any other issue.

In presence or use cases, the Covered Horse will be subject to a period of ineligibility, the length of which depends on the particular Banned Substance(s) detected, as set out in the Prohibited List. During any period of ineligibility, the Covered Horse shall not participate in any Workout or Covered Horserace, but will remain subject to testing (Rule 3229).

The Covered Person will be sanctioned with a period of ineligibility commensurate to his or her level of fault, in accordance with a detailed sanctioning framework. The starting point for presence, use, possession, or administration violations is a period of

ineligibility of two years, subject to elimination or reduction if the Covered Person can demonstrate that he or she bears no or no significant fault or negligence, or subject to increase if aggravating circumstances are present (Rules 3223(b), 3224, and 3225). For other violations, the rules specify other starting points or ranges for the applicable period of ineligibility that reflect the seriousness of the violation (Rule 3223(b)). The rules also provide the Authority with the ability to eliminate or reduce an applicable period of ineligibility in circumstances where a Covered Person provides Substantial Assistance or admits the violation early or in the absence of other evidence (Rule 3226). There are also increased sanctions for repeat offenders (Rule 3228). During any period of ineligibility, the Covered Person shall not participate in any capacity in any activity involving Covered Horses or in any other activity (other than authorized anti-doping education or rehabilitation programs) taking place at a Racetrack or Training Facility; nor shall he or she permit anyone to participate in any capacity on his or her behalf in any such activities (Rule 3229(a)). The Covered Horse(s) of an Owner or Trainer subject to a Provisional Suspension or period of Ineligibility shall also be subject to restrictions (Rule 3229(b)).

The Covered Person may also be required to pay a fine, depending on the violation, and some or all of the Agency's legal costs (Rule 3223(b)).

Where a Covered Person is found based on the same facts to have committed a violation involving both (i) one or more Banned Substance(s) or Banned Method(s), and (ii) one or more Controlled Medication Substance(s) or Controlled Medication Method(s), the Covered Person shall be considered to have committed one Anti-Doping Rule Violation and the sanction imposed shall be based on the Banned Substance or Banned Method that carries the most severe sanction. Rule 3227 (Aggravating Circumstances) may also be applied to increase the sanction imposed (Rule 3228(d)).

The Equine Anti-Doping Rules provide a framework for the results management of potential anti-doping rule violations, as directed by the Act. Different types of Samples may be collected from Covered Horses, including urine, blood, and hair. Unless specified otherwise in the rules, at the time of collection, the Sample will be divided into an ''A'' and a ''B'' Sample. Review of ''A Sample'' adverse analytical findings or other evidence leads to an initial notification by the Agency to the Covered Person that he or she may have committed an anti-doping rule violation (Rule 3245). In some cases, the Covered Person will be provisionally suspended pending determination of the matter (Rule 3247), and the ''B Sample'' may be tested (Rule 3246). The Covered Person is entitled to respond to the Agency's initial notification, and if he or she does, the Agency will take any comments and additional information into account before deciding whether to formally charge the Covered Person with an anti-doping rule violation and request a more formal response (Rule 3248)).

The Covered Person is entitled to have the charge determined by the Arbitral Body (the panel hearing will consist of either one or three impartial arbitrators) in accordance with the Arbitration Procedures (Series 7000). The final decision of the Arbitral Body is subject to review in accordance with the Act (Rule 3264). The rules also provide for the Agency and Covered Person to agree to a resolution to the charge without a hearing (Rule 3249).

4. Equine Controlled Medication Rules—Rules 3310–3360

The Equine Controlled Medication Rules set out in Chapter IV of the Protocol apply to conduct involving Controlled Medication Substances or Controlled Medication Methods (*i.e.,* substances prohibited for use on or administration to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample or Post-Work Sample, except as otherwise specified in the Prohibited List). The violations set out in this Chapter are drawn from similar provisions to those relating to Anti-Doping Rule Violations, modified to reflect the differing approaches to the use of Controlled Medication Substances and Controlled Medication Methods, as opposed to Banned Substances and Banned Methods. The violations include the use, possession, or administration to a Covered Horse of Controlled Medication Substances or Controlled Medication Methods during the Race Period (Rules 3313 and 3315). Other violations include use of a Controlled Medication Substance that is not justified by the horse's medical condition or does not meet other criteria (Rule 3314), tampering with medication control (Rule 3316), and the presence of a Controlled Medication Substance in a sample collected from a Covered Horse (Rule 3312). In accordance with section 3057(a)(2) of the Act, presence and use violations are considered strict liability offenses. Attempts to commit Controlled Medication Rule Violations are also sanctionable.

As directed by the Act, the Authority has developed a list of civil sanctions for Controlled Medication Rule Violations. The Protocol and Prohibited List establish uniform rules imposing civil sanctions against Covered Persons and Covered Horses for Controlled Medication Rule Violations, as directed by section 3057(d) of the Act. The range of civil sanctions (a) take into account the unique aspects of horseracing; (b) are designed to ensure fair and transparent Covered Horseraces; and (c) are intended to deter violations. The severity of the sanctions depends on the nature of the violation, and allows an opportunity for adjustment depending on the violation and facts involved.

A mandatory part of each sanction will include Public Disclosure of relevant information, including the Covered Person's name, the violation, and consequences imposed (Rules 3331 and 3620).

If the violation arises from a Post-Race Sample or occurs during the Race Period, the Covered Horse's results at that Covered Horserace will automatically be disqualified, with all resulting consequences, because the horse competed with a Controlled Medication Substance in its system. The results will be automatically disqualified irrespective of the reason why the Controlled Medication Substance was detected or of any degree of fault on the part of the Covered Person (Rule 3321(a)). Subsequent results will not be disqualified (Rule 3321(b)).

The Covered Horse will not be subject to a period of ineligibility if the violation involves a Controlled Medication Substance, but may be subject to a period of ineligibility if the violation involves a Controlled Medication Method as specified in the Prohibited List (Rule 3322).

Covered Persons shall be sanctioned for any Controlled Medication Rule Violations in accordance with Rule 3323(b), depending on the category or class of the violation, and the number of violations committed within that same category/class in the previous two-year period. Presence, use, and administration violations are divided into three different classes (Class A, Class B, Class C) with Class A carrying the more severe sanctions. The sanctions for Controlled Medication Rule Violations are subject to elimination (Rule 3324), reduction (Rules 3325 and 3326), or increase (Rule 3327), depending on the violation in issue and the specific circumstances of the case.

The Protocol also establishes a multiple medication violation penalty

points system for repeat offenders which takes account of violations committed in different categories/classes (Rule 3328). As directed by section 3055(g) of the Act, the Authority used the Association of Racing Commissioners International penalty and multiple medication violation rules, Model Rules of Racing, as a baseline for the multiple violations penalty points system. All adjustments and modifications to the baseline rules were approved by the Authority in consultation with the ADMC and the Agency in accordance with section 3055(g)(3) of the Act.

The penalty points system is not a substitute for the consequences that apply to the underlying Controlled Medication Rule Violations. Rather, the penalty points system is intended to apply additional uniform Consequences where the Covered Person is a repeat offender and exceeds the permissible number of points. Where the relevant cumulative point threshold is exceeded, the Covered Person shall receive an automatic additional period of ineligibility as specified in Rule 3328(c). Penalty points are assigned automatically depending on the category/class of violation in issue, save where specified otherwise in Rule 3328. Penalty points and the additional period of Ineligibility shall be applied automatically at the conclusion of the proceeding on the underlying violation, without any additional hearing or right of review. Penalty points shall be applied retroactively to start on the date on which the Controlled Medication Rule Violation occurred and shall expire after 2 years (Rule 3328(d)).

During any period of Ineligibility or Provisional Suspension, Covered Persons shall be prohibited from the same activities as anyone banned for an Anti-Doping Rule Violation. As for Anti-Doping Rule Violations, the Covered Horses of a suspended Trainer or Owner may not participate in any Timed and Reported Workout or Covered Horserace, but in contrast to Anti-Doping Rule Violations, they may participate in a Covered Horserace if they were entered in the race before the Trainer was notified of the Provisional Suspension or the period of Ineligibility was imposed (whichever is earlier) (Rule 3320(b)). Further, in contrast to Anti-Doping Rule Violations, the Covered Horses of a suspended Trainer must only be transferred to another Covered Person if the period of ineligibility imposed on the Trainer is more than 30 days (Rule 3329(b)).

The Covered Person may also be required to pay a fine depending on the category of the violation, and some or all of the Agency's legal costs (Rule 3323(b)).

The Equine Controlled Medication Rules provide a framework for the results management of potential controlled medication rule violations as directed by the Act, from review of ''A Sample'' adverse analytical findings or other evidence leading to an initial notification by the Agency to the Covered Person that he or she may have committed a controlled medication rule violation (Rule 3345). The Covered Person will not be provisionally suspended pending determination of the matter unless he or she voluntarily accepts a provisional suspension (Rule 3347), and the B Sample may be tested (Rule 3346). The Covered Person is entitled to respond to the Agency's initial notification, and if he or she does, the Agency will take any comments and additional information into account before deciding whether to formally charge the Covered Person with a controlled medication rule violation and request a more formal response (Rule 3348).

The Covered Person is entitled to request a hearing before the Internal Adjudication Panel. The hearing will ordinarily be conducted before a single member of the Internal Adjudication Panel, though three members may be assigned to hear the case where appropriate. The Internal Adjudication Panel may decide in its sole discretion to determine the matter on the written submissions alone without a hearing if the Internal Adjudication Panel considers itself sufficiently well-informed to render a decision on the written submissions alone. The Internal Adjudication Panel will issue a final decision, subject to review in accordance with the Act (Rules 3361–3364).

The rules also provide for the Agency and Covered Person to agree to a resolution to the charge without a hearing (Rule 3349).

5. Other Violations and General Procedure/Administration—Rules 3500–3800

Chapter V sets out additional disciplinary offenses that do not fall within the chapters on Equine Anti-Doping Rules or Equine Controlled Medication Rules (Rule 3510), and also prescribes sanctions (periods of ineligibility and fines) for those violations (Rule 3520). Those violations include engaging in disruptive or offensive conduct towards doping control personnel, refusing/failing to cooperate in full with the Authority or Agency in the discharge of his or her respective responsibilities under this Protocol, and committing a whereabouts failure (in effect, failing to provide the necessary information to enable a Covered Horse to be located for testing). Alleged violations will be determined by the Internal Adjudication Panel (Rule 3361).

In accordance with section 3057(c)(2) of the Act, the rules provide guidelines for confidentiality and public reporting of decisions (Rules 3610–3630). Rule 3710 also provides for the recognition of decisions by recognized, official third parties, for example, national horseracing authorities in other countries applying substantially similar rules (Rule 3700).

c. Terms of Substance: Rule Series 1000—General Provisions

The Protocol and other Series are supported by the general rules of interpretation (Rule 1010) and a list of defined terms (Rule 1020) to assist with clarity of meaning.

d. Terms of Substance: Rule Series 4000—Prohibited List

As directed by sections 3053 and 3055 of the Act, the Authority has developed a list of permitted and prohibited medications, substances, and methods, including allowable limits of permitted medications, substances, and methods, using as a baseline 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 (''IFHA''), including the IFHA International Screening Limits for urine and the IFHA International Screening Limits for plasma. All adjustments and modifications to the baseline rules were approved by the Authority in consultation with the ADMC and the Agency in accordance with section 3055(g)(3) of the Act.

The Prohibited List identifies Prohibited Substances and Prohibited Methods that are: (a) prohibited at all times (''Banned Substances'' and ''Banned Methods'') on the basis of the Agency's determination that medical, veterinary, or other scientific evidence or experience supports their actual or potential (i) ability to enhance the performance in Covered Horses, (ii) masking properties, or (iii) detrimental impact on horse welfare; or (b) prohibited for Use on or Administration to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample (which includes samples collected following a Covered Horserace or Vets' List Workout) or Post-Work Sample (which includes samples collected following a Timed

and Reported Workout), except as otherwise specified in the Prohibited List (''Controlled Medication Substances'' and ''Controlled Medication Methods''). Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (*e.g.,* anabolic steroids) or by specific reference to a particular substance or method.

The Prohibited List is supplemented by the ''Technical Document—Prohibited Substances,'' which enumerates the Prohibited Substances that fall into the general categories listed in the Prohibited List and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical Document also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and that are therefore subject to more flexible sanctions.

In accordance with section 3055(d) of the Act, the use or administration of Controlled Medication Substances and Controlled Medication Methods is prohibited during the ''Race Period'' (*i.e.,* 48 hours prior to post-time) except where expressly provided otherwise in the Prohibited List or Protocol. Responsible Persons are strictly liable for any substance found to be present in a Post-Race Sample or Post-Work Sample, even if such substance was used or administered before the Race Period. As specified in section 3055(e) and (f) of the Act, certain exemptions apply to furosemide (*i.e.,* Lasix/Salix), which are set out in the Prohibited List.

The Prohibited List and supporting Technical Document were prepared in consultation with the ADMC and the Agency, and approved by the Authority, as directed by section 3055(c)(5) of the Act. In preparing the Prohibited List and the ''Technical Document—Prohibited Substances,'' the Authority considered lists of prohibited substances and methods published by other organizations, including the ARCI, WADA, the FEI, and the British Horseracing Association. Documents considered in preparing the Prohibited List are exhibited below:

Exhibit B.7. IFHA International Screening Limits for urine.

Exhibit B.8. IFHA International Screening Limits for plasma.

Exhibit B.9. ARCI Uniform Classification Guidelines for Foreign Substances and Recommended Penalties Model Rule.

Exhibit B.10. WADA 2022 Prohibited List.

Exhibit B.11. 2022 FEI Equine Prohibited Substances List.

Exhibit B.12. British Horseracing Association Equine Prohibited List Code (2022).

Exhibit B.13. British Horseracing Association Published Detection Times (June 2019).

Exhibit B.14. Hong Kong Jockey Club Medication and Prohibited Substances.

The ADMC also considered a number of scientific papers when developing the Prohibited List and supporting Technical Document:

Exhibit B.15. AAS 16 Detection of Some Designer Steroids in Horse Urine: Identifies the integrity risks associated with the use of anabolic steroids in racehorses.

Exhibit B.16. AAS 29 Anabolic Effects of β2-agonists, formoterol and salbutamol on cancellous bone of ovariectomized (OVX) rat: With the banning of anabolic steroids, those seeking an anabolic effect turned to β2-agonists. Their misuse has been well-documented in horses engaged in racing and training.

Exhibit B.17. ACA 01 Effects of intravenous aminocaproic acid on exercise-induced pulmonary haemorrhage (EIPH): Although this drug has extensive anecdotal support for effect in mitigating EIPH, this article demonstrates no effect on the condition. While not regulated in human sport, the illicit use of this substance, particularly in races where furosemide is prohibited, represents an integrity threat.

Exhibit B.18. AU 04 Disposition of the anti-ulcer medications ranitidine, cimetidine, and omeprazole following administration of multiple doses to exercised Thoroughbred horses. The results of multiple RMTC administration studies supporting the use of anti-ulcer medications up to 24 hours prior to a horse's race.

Exhibit B.19. Bicarb 08 Sodium Bicarbonate as an Ergogenic Aid: Supports the use of alkalinizing agents as a Prohibited Method.

Exhibit B.20. BP Gen 04 Bisphosphonate Therapy in Equine Sports Medicine: While having legitimate use in human medicine, the documented pharmacologic effect of this class of drug (blocking remodeling) on bone represents a significant increased risk for fracture development in the racehorse.

Exhibit B.21. Cobalt 01 The Disparate Roles of Cobalt in Erythropoiesis, and Doping Relevance: Establishes the relevance of the administration of cobalt salts as a doping threat and justifies the controls established in the Prohibited List.

Exhibit B.22. Comp 18 The Disparate Roles of Cobalt in Erythropoiesis, and Doping Relevance: Published by the American Veterinary Medical Association, this document clarifies what constitutes legal compounding of drugs as the ethical use of compounded medications is important to maintaining equine health. However, the compounding or administration of illicitly compounded substances to circumvent FDA oversight represents a substantial risk to horse health and racing integrity.

Exhibit B.23. EIPH 33 Exercise-induced pulmonary hemorrhage (EIPH): mechanistic bases and therapeutic interventions: Describes this condition (rarely, but occasionally, experienced by human athletes) that affects virtually every race horse at some point(s) in its racing and training career.

Exhibit B.24. Furos 15 Efficacy of furosemide in the treatment of exercise-induced pulmonary hemorrhage in Thoroughbred racehorses: The seminal study that demonstrated the efficacy of furosemide in mitigating or preventing episodes of EIPH in the racing Thoroughbred. While not submitted as a justification for the continued use of furosemide, this study did establish furosemide as the only medication having efficacy for controlling EIPH and why the WADA total ban on furosemide cannot be, at this time, applied to horseracing. This article also then justifies the Prohibited List's exclusion for the use of furosemide in training exercise.

Exhibit B.25. PAG 13 Intra-Articular Polyacrylamide Hydrogel Injections Are Not Innocent: While the use of polyacrylamide hydrogels have a history of use in human joint disease, their introduction into the equine market as medical devices, is relatively recent, and the lack of documented method of action causes reservations about its use in that it may have the potential to mask pain and allow the progression of orthopedic disease to the overall detriment of the horse.

Exhibit B.26. PBZ 05 Effectiveness of administration of phenylbutazone alone or concurrent administration of phenylbutazone and flunixin meglumine to alleviate lameness in horses: Establishes justification for the prohibition on ''stacking'' of NSAIDs—medications that are not controlled in human sport but require control in equine sport for safety reasons and ethical considerations.

Exhibit B.27. Ract 04 Effects of Ractopamine HCl on Physical and Reproductive Parameters in the Horse: This anabolic agent is not addressed in human sport but has been detected in post-race and out of competition samples derived from racehorses. Its presence has been both the result of

contamination of commercial feed at the processing site as well as deliberate administration.

Exhibit B.28. Thyro 07 A randomised, controlled trial to determine the effect of levothyroxine on Standardbred racehorses: This prescription medication had widespread use for the (scientifically unsupported) treatment of a multitude of conditions—other than hypothyroidism which is exceedingly rare in the horse. This article elucidates the health risk in its use and justifies the ban as established in the Prohibited List.

Exhibit B.29. Tryp 03 Effects of a commercial dose of L-tryptophan on plasma tryptophan concentrations and behaviour in horses: An example of unregulated, over the counter oral nutraceuticals that have the potential to impact a horse's health, behavior, or mental state—thus exerting a drug-like effect while evading regulation by the FDA. It is for this reason that the Prohibited List is not permissive of the use of these substances during the race period, to be consistent with FDA-approved drugs having similar effects.

1. Banned Substances and Banned Methods—Rule Series 4100

Banned Substances and Banned Methods are set out in categories, including anabolic agents, peptide hormones and growth factors, beta-2 agonists, hormone and metabolic modulators, and diuretics and masking agents (Rule 4110). Banned Methods include blood manipulation, chemical castration or immunocastration, and gene and cell doping (Rule 4120).

2. Controlled Medication Substances and Controlled Medication Methods and Exceptions—Rule Series 4200

Subject to exceptions specified in the Prohibited List (Rule 4212), only feed, hay, and water are permitted during the Race Period (Rule 4211(a)). Accordingly, subject to Rule 4212, any substance administered during the Race Period or present in a Post-Race Sample (including any metabolite(s), artifact(s), and isomer(s) of such substance(s)) that does not otherwise qualify as a Banned Substance shall constitute a prohibited Controlled Medication Substance. In addition, certain Controlled Medication Substances are prohibited from presence in a Post-Work Sample (Rule 4211(b)). Exceptions are provided in Rule 4212 for emergency veterinary care, for certain substances that are permitted up to 24 hours prior to Post-Time (*e.g.,* anti-ulcer medications), electrolyte solutions consumed by the horse by free choice, furosemide (*i.e.,* Lasix/Salix), and for supplements or feed additives that do not have an action or effect on listed mammalian body systems.

Controlled Medication Methods include alkalinization, intra-articular injections, and use of a nasogastric tube within specified time periods (Rule 4220).

3. Ineligibility Periods for Covered Horses—Rule Series 4300

Consistent with section 3057(d) of the Act, Rule 4300 establishes uniform rules setting out the periods of ineligibility that apply to Covered Horses implicated in Anti-Doping Rule Violations or Controlled Medication Rule Violations. The ineligibility period ranges from zero months to lifetime bans, depending on the category of the substance or method.

Violations involving Controlled Medication Substances will not result in a period of Ineligibility for the Covered Horse. However, the Covered Horse shall be placed on the Veterinarians' List and a Vets' List Workout must be scheduled (at which the horse may be subject to Sample collection). Violations involving Controlled Medication Methods may result in a period of Ineligibility for the Covered Horse where specified in the Prohibited List at Rule 4320.

Covered Horses are not subject to increased ineligibility periods if they are involved in multiple violations.

4. Rule Series 4000 Appendix: Technical Document—Prohibited Substances

The ''Technical Document—Prohibited Substances'' supplements the Prohibited List (Rule Series 4000), and sets out additional detail concerning Prohibited Substances. The ''Technical Document—Prohibited Substances,'' enumerates specific Prohibited Substances that fall into the general categories listed in the Prohibited List and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical Document also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and that are therefore subject to more flexible sanctions. The following paragraphs describe the rules and specifications applicable to certain categories of medications that vary from the baseline standards enumerated in 15 U.S.C. 3055(g).

i. Anti-Ulcer Medications (Cimetidine, Omeprazole, Ranitidine)

The IFHA has published a restricted administration period that prohibits administration of anti-ulcer medications within 48 hours of the post time for the race in which the horse is entered. HISA in the Protocol recommends a 24-hour restricted administration period.

The basis for this deviation is two-fold: (1) Withdrawal intervals of greater than 24 hours have been identified as an equine welfare issue. Published research demonstrates a rebound effect when anti-ulcer medications are withdrawn for more than 24 hours with resultant ulcers more severe than those originally treated. (2) The IFHA's Advisory Council on Prohibited Substances and Practices will be revisiting the control of these substances at its December 2022 meeting, and it is anticipated that the international community will adopt a withdrawal interval strategy similar to the one proposed by HISA.

ii. NSAIDs (Flunixin, Ketoprofen, Phenylbutazone)

The IFHA has published a 48-hour Detection Time (DT) for a single NSAID—meclofenamic acid. There is no FDA-approved product containing meclofenamic acid commercially available in the United States. (It is important to note that a Detection Time is the foundation for determining a withdrawal interval, but under no circumstances should the Detection Time be equated with withdrawal guidance. The withdrawal interval is decided by the veterinarian in consultation with the responsible person for the horse in consideration of their level of risk aversion and their knowledge of the specific horse's health, management, other medications or foreign substances co-administered, and other relevant factors. The withdrawal interval should always be longer than the Detection Time, and in most cases this means adding 24 hours (at a minimum) to the Detection Time.)

The HISA Protocol establishes Screening Limits corresponding to a 48-hour Detection Time for 3 commercially available NSAIDs having FDA-approval for use in the horse. The Protocol allows the veterinarian to select one NSAID that can be administered using a withdrawal interval based on the 48-hourr Detection Time. All other NSAIDs are then controlled applying IFHA Detection Times and Screening Limits, and the detection of more than one NSAID in a horse's sample is a violation. This is philosophically consistent with the IFHA and represents a far more restrictive approach to the use of NSAIDs than currently exists in the United States.

iii. Methocarbamol/Glycopyrrolate

The IFHA is silent on these substances. However, the Asian Racing Federation (a signatory to the IFHA's

International Agreement on Breeding, Racing, and Wagering (IABRW)) has published a Screening Limit for methocarbamol. So there is precedent for establishing Screening Limits in addition to those provided by the IFHA. Further, the IFHA's IABRW references the adoption of Screening Limits and advises that a regulatory authority may elect to publish Detection Times.

The Screening Limits and Detection Times for methocarbamol and glycopyrrolate were derived after reviewing the Racing Medication and Testing Consortium's administration study pharmacokinetic data. The elected Screening Limits and corresponding Detection Times ensure withdrawal intervals of sufficient length to prevent the substances from having any potential to impact a horse's racing performance.

iv. Ciclesonide/Lidocaine

The Protocol adheres to IFHA Screening Limits, but, consistent with the requirements of IABRW Article 6, HISA has elected to adopt Detection Times that vary from those of the IFHA. In the case of ciclesonide, the Detection Time is consistent with that used by Racing Australia (also an IFHA member). For lidocaine, HISA elected to use a lower dose in determining a Detection Time, as it believed that IFHA's dosing is too permissive and potentially allows illicit low-dose use on Race Day, which may be undetectable by laboratory testing.

v. Procaine Penicillin

The European Horseracing Scientific Liaison Committee (EHSLC) has established a detection time of 240 hours (10 days) for procaine penicillin. (The EHSLC is the scientific body that the IFHA consults when developing medication control policy). HISA has determined that the 240-hour detection time could negatively impact horse welfare, through the withholding of appropriate medical treatment. HISA has elected instead to adopt the current ARCI controls, which allow for the use of this safe and effective antibiotic up to 48 hours prior to a race, while still effectively controlling against the illicit use of procaine as a local anesthetic.

e. Terms of Substance: Rule Series 5000—Equine Standards for Testing and Investigation

In accordance with section 3055 of the Act, the Authority has developed Equine Standards for Testing and Investigations to manage test distribution planning (including intelligence-based testing), the sample collection process, and in-competition and out-of-competition testing. The Authority considered the Association of Racing Commissioners International out-of-competition testing standards as a baseline, but also relied in large part on the WADA International Standard for Testing and Investigations, given the comprehensive nature of that standard. All adjustments and modifications to the baseline rules were approved by the Authority in consultation with the ADMC and the Agency in accordance with section 3055(g)(3) of the Act.

In preparing the standards, the Authority consulted with the Agency, the ADMC, and experts in the field to tailor the standards to horseracing. The Authority considered and relied significantly on the following rules:

Exhibit B.2. The ARCI out-of-competition testing standards, Model Rules of Racing (version 11.0). The Authority notes that the Act refers to version 9.2, but the model rules have since been updated. The most recent versions of the ARCI documents are available at *https://www.arci.com/model-rules-standards/.*

Exhibit B.30. WADA International Standard for Testing and Investigations dated January 1, 2021. The most recent versions of the WADA documents are available at *https://www.wada-ama.org/en/resources/.*

1. Testing—Rules 5100–5500 and 5800

The Testing and Investigations Standards sets out how the Agency will plan effective testing by using risk assessments and prioritizing between Covered Horses and types of testing (Rule 5100). As directed by section 3055(c)(4)(C) of the Act, Sample Collection Personnel will notify the Responsible Person or Nominated Person without advance notice that his or her Covered Horse has been selected for testing (Rule 5200), following—as applicable—the procedure set out at Rule 5220 depending on when the sample is collected.

Sample Collection Sessions will be conducted by suitably qualified personnel (Rule 5450), using suitable equipment (Rule 5320), in a suitable ''test barn'' environment (Rule 5310). Samples will be collected in accordance with Rule 5400, in particular to ensure that the sample is of suitable quality and quantity, is clearly and accurately identified, is sealed in a tamper evident kit, and has not been manipulated or tampered with. Further specific procedures and requirements apply to the collection of urine samples (Rule 5420), blood samples (Rule 5430), and hair samples (Rule 5440).

Once collected, Samples will be stored and transported by Sample Collection Personnel in a manner that protects the integrity, identity, and security of the Samples (Rules 5510 and 5520).

2. Investigations—Rule 5600–5700

As directed by the Act, the Agency will put in place internal processes and procedures to ensure it is able to gather, analyze, and process anti-doping and medication control intelligence from all available sources in order to help deter and detect doping and medication abuse, to inform effective, intelligent, and proportionate test distribution planning, to plan intelligence-based Target Testing, and to conduct investigations (Rule 5600).

Further, the Agency will conduct efficient and effective investigations into (among other things) atypical findings and other sample abnormalities, and other analytical or non-analytical information or intelligence. The purpose of such investigations is to either rule out or develop evidence that supports an anti-doping or controlled medication rule violation or other violation of the Protocol (Rule 5710). The Agency will make use of all investigative resources available to it, which may include obtaining information from law enforcement authorities and other regulators (Rule 5730). The Agency may also exercise the investigative powers conferred under applicable rules, including powers of inspection, examination, seizure, production of documents, request to the Authority for the issuance of subpoenas, and the conduct of interviews). All Covered Persons are required to cooperate with the Agency's investigations in the manner set forth in the rules, and failure to cooperate may result in the imposition of sanctions (Rule 5720(f)).

f. Terms of Substance: Rule Series 6000—Equine Standards for Laboratories and Accreditation

As directed by sections 3053, 3055, and 3057 of the Act, the Authority has developed the Equine Standards for Laboratories and Accreditation (''Laboratory Standards'') using the WADA International Standard for Laboratories as a baseline. All adjustments and modifications to the baseline rules were approved by the Authority in consultation with the ADMC and the Agency in accordance with section 3055(g)(3) of the Act.

Exhibit B.31. WADA International Standard for Laboratories dated January 1, 2021. The Authority notes that the Act refers to the WADA International Standard for Laboratories (version 10.0) dated November 12, 2019, but that

version has since been updated by WADA. The most recent versions of the WADA documents are available at: *www.wada-ama.org/en/resources/.*

As directed by the Act at section 3057(b), the Laboratory Standards establish standards of accreditation for laboratories involved in testing samples from Covered Horses; the process for achieving and maintaining accreditation; and the standards and protocols for testing of such samples. The Laboratory Standards will be supported by technical documents, letters, notes, and laboratory guidelines, as appropriate.

The Laboratory Standards also cross refer in a number of places to the ISO/IEC 17025 standard. Laboratories must obtain ISO/IEC 17025 accreditation before receiving HISA Equine Analytical Laboratory (''HEAL'') accreditation.

Exhibit B.32. ISO/IEC 17025:2017.

The Authority consulted with laboratory experts in order to tailor the Laboratory Standards to horseracing laboratories and to reflect the specificities of equine sport. As part of its review, the Authority considered the ILAC–G7:04/2021 Accreditation Requirements and Operating Criteria for Horseracing Laboratories, which may inform subsequent Technical Documents.

Exhibit B.33. ILAC–G7:04/2021 Accreditation Requirements and Operating Criteria for Horseracing Laboratories. The most recent versions of the ILAC standards are available at: *https://ilac.org/publications-and-resources/ilac-guidance-series/.*

1. Laboratory Accreditation—Rule Series 6100 and 6500

In accordance with sections 3055(c) and 3057(b) of the Act, the Laboratory Standards establish the requirements for obtaining HISA Equine Analytical Laboratory (''HEAL'') accreditation, and the requirements and standards for maintenance of HEAL accreditation. The rules set out a procedure by which laboratories may achieve HEAL accreditation, starting with an application and the granting of ''candidate laboratory'' status. The candidate laboratory must provide specified information to the Agency, perform pre-probationary testing to identify prohibited substances in samples, and complete an on-site assessment. The Agency will assess the outcomes of those processes and any non-conformities identified, and the candidate laboratory will have a specified period of time to remedy those non-conformities with corrective actions (Rule 6110).

If a candidate laboratory is granted probationary accreditation status, it will be accredited by the Agency, with a probationary period of two years or until analysis of 2,500 samples has been performed, whichever occurs first. If the probationary period is successfully completed and the laboratory successfully completes a final accreditation test, the Agency will grant accreditation to the laboratory (Rule 6120).

The rules impose continuing obligations on each laboratory that must be satisfied in order to maintain HEAL accreditation (Rule 6130), including maintenance of ISO/IEC 17025 accreditation, satisfactory participation in the Agency External Quality Assessment Scheme (''EQAS'') whereby laboratories are sent samples to be analyzed (blind or for specified substances), compliance with the code of ethics (which is set out in full at Rule 6600), and continued research and development activities and sharing of knowledge.

The Agency will regularly monitor and review the compliance of each laboratory with its ongoing accreditation obligations (Rule 6140). A laboratory's HEAL accreditation may be suspended or revoked, or subjected to specified analytical testing restrictions if (among other things) the laboratory fails to comply with the Laboratory Standards or other Agency requirements (Rules 6510 and 6520). The rules set out the effects of such decisions on Agency-related laboratory activity and the transfer of samples to other laboratories pending resolution of the matter (Rule 6560), and provide for reinstatement of the laboratory if it has remedied the non-compliance that resulted in the Agency's decision.

2. Laboratory Quality Monitoring—Rule Series 6200, 6400, and 6600

The Agency will regularly distribute External Quality Assessment Scheme (EQAS) samples in order to monitor the capabilities of laboratories and probationary laboratories, evaluate their proficiency, and improve test result uniformity between laboratories (Rule 6210). Some of these samples are blind (the laboratory will know it is an EQAS sample but will not know its contents), some are double-blind (the laboratory will not know it is an EQAS sample or know its contents), and some are educational (the laboratory will know it is an EQAS sample and will know its contents) (Rule 6220). EQAS samples should be analyzed in a manner substantially similar to that applied to routine samples, unless otherwise specified by the Agency, and results reported to the Agency (Rules 6250 and 6260).

The Agency will evaluate laboratory EQAS results and, as necessary and appropriate, inform the laboratory of any technical, methodological, or clerical errors that should be remedied. If such errors are remedied, no penalty will be imposed (Rule 6410). The Agency may request corrective action reports that detail actions taken to correct any non-conformity or other issue (Rule 6420). The annual EQAS evaluation will be a factor in assessment of HEAL accreditation and maintenance of HEAL accreditation.

3. Analysis of Samples—Rule Series 6300

The Laboratory Standards set out a process for the withdrawal of accreditation if the relevant requirements and standards are not met. The Laboratory Standards also ensure that laboratories report valid test results based on reliable evidentiary data and facilitate harmonization in analytical testing of Samples by laboratories.

The rules also contain detailed standards for the analysis of samples (section 6300). When analyzing a sample, the laboratory will prepare an aliquot, select the analytical testing procedure, and conduct the initial testing procedure, with the objective of obtaining information about the potential presence of prohibited substances in the sample (Rule 6308). The laboratory will then conduct the confirmation procedure to obtain a result that either supports or does not support the reporting of an adverse analytical finding or atypical finding, in particular, by identifying and sometimes quantifying—for example in the case of a threshold substance—a prohibited substance in the sample (Rules 6309 and 6311). The laboratory must conduct a detailed review of the analysis (Rule 6315) and report all results to the Agency (Rule 6316).

An important amendment to the baseline rules is that any B sample analysis will be conducted by a different laboratory than the one that performed the A sample analysis, unless the Agency considers that is not possible due to (i) reasonable concerns over Sample integrity or unstable analytes; or (ii) because no other Laboratory is available to perform the B Sample procedure within a reasonable period of time (Rule 6312).

If the laboratory reports an adverse analytical finding for the A sample, and the Covered Person requests or the Agency orders that the B sample be analyzed, the laboratory will promptly transfer the B sample to the laboratory

specified by the Agency, and that (second) laboratory will perform the B sample procedure and analysis (Rule 6312). The samples will be stored and may be subject to further analysis if directed by the Agency (Rules 6313 and 6319).

e. Terms of Substance: Rule Series 7000—Arbitration Procedures

In accordance with sections 3053(a)(10) and 3057(c) of the Act, the Arbitration Procedures set out a disciplinary process for the hearing and adjudication of Anti-Doping Rule Violations, Controlled Medication Rule Violations, and other related offenses. As directed by section 3057(c)(3), the procedures were developed to provide for adequate due process, including impartial hearing panels commensurate with the seriousness of the alleged violation. Different procedures apply to Anti-Doping Rule Violations (heard by the Arbitral Body) as compared to Controlled Medication Rule Violations (heard by the Internal Adjudication Panel, which may adjudicate the matter on written submissions alone.

1. Dispute Resolution Frameworks—Rules 7010–7050

The arbitrators on the Arbitral Body will be appointed by the Agency for four-year terms (Rule 7030). Members of the Internal Adjudication Panel will be appointed by the Agency for four-year terms (Rule 7040). Members of the Arbitral Body and Internal Adjudication Panel will receive mandatory annual training and education on issues relating to the proper handling of cases (Rule 7050).

2. Initiating Proceedings—Rules 7060–7160

If a Covered Person is charged with an Anti-Doping Rule Violation or Controlled Medication Rule Violation, proceedings will be initiated with the appropriate adjudicator by the Agency. The adjudicator will be appointed by the arbitral body or by the coordinator of the Internal Adjudication Panel, as applicable (Rule 7130), and the rules establish a process by which parties may challenge the adjudicator's appointment in appropriate circumstances. The adjudicator has broad powers to manage the proceedings, including the power to issue orders for expedited procedures, rule on their own jurisdiction, and consolidate proceedings.

3. Hearings and Evidence—Rules 7170–7330

In cases involving Anti-Doping Rule Violations or related violations, the rules set out a procedure for the exchange of written submissions and evidence (Rule 7170), and for the conduct of hearings (Rule 7250). The Arbitral Body has broad discretion to determine the admissibility, relevance and materiality of evidence offered, and may, if necessary and appropriate, order production (Rule 7260 and 7270) or interim measures (Rule 7280) or resolve challenges to provisional suspensions at a provisional hearing (Rule 7290).

In cases involving Controlled Medication Rule Violations and related violations, and other violations of the Protocol, a more streamlined and flexible process applies (Rule 7180).

4. Decisions—Rules 7240–7450

In all cases, a final decision will be issued and the adjudicator may grant any remedy or relief authorized by the Protocol (Rule 7340–7350). Final decisions issued by the Arbitral Body or Internal Adjudication Panel are subject to review as specified in section 3058 of the Act (Rule 7400).

III. Self-Regulatory Organization's Summary of Comments Received Pre-Submission and Its Responses to Those Comments

As encouraged by the Commission's procedural rule, the Authority, before finalizing this submission to the Commission, made a draft of the Anti-Doping and Medication Control proposed rule available to the public for review and comment on the HISA website, *https://www.hisausregs.org/,* beginning on June 1, 2022. Comments on the Anti-Doping and Medication Control proposed rule were received from various individuals and groups in the horseracing industry.

The stakeholder feedback received was constructive and well-considered. All submitted comments were carefully reviewed by the Authority as well as by the ADMC and the Agency. Those collected comments are available as Exhibit A on the docket at *https://www.regulations.gov.* The Authority also engaged with a number of stakeholders through follow-up conference calls to further analyze their comments and discuss any questions raised. The stakeholder comments informed a number of adjustments and modifications to the proposed rules, as explained in more detail below. The open consultation process and stakeholder engagement is an important process and one that is intended to build consensus where possible within the industry.

The following is a summary of the substance of the comments received. The following also summarizes the Authority's response to the significant issues raised in the comments, and the manner in which the Authority has addressed those comments in developing the proposed rules submitted to the Commission. In a few instances the Authority declined to make a suggested change, though the Authority will consider the suggestions made in the course of future rulemaking.

1000 Series—General Provisions

The Authority revised the definition of ''Race Day'' based on comments received, amending it so that the period will end one hour after the end of the Official Workout or Covered Horserace or at the end of any Sample collection process, whichever is later, instead of ending at 23:59 (11:59 p.m.) on the day of the Official Workout/Covered Horserace as previously stated. This revision was made to take account of horse welfare, recognizing in particular that once a horse has been subject to sample collection, or it has been decided that a horse will not be selected for sample collection, the horse should not be prohibited from receiving any necessary therapeutic treatments post-race that are permitted outside the Race Period. The end of the ''Race Day'' now also coincides with the end of the ''Race Period.''

The definition of ''Tampering'' was adjusted to make clear that it does not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification. This addition mirrors the wording used in the definition of ''Administration,'' which includes the same important carve-out.

3000 Series—Equine Anti-Doping and Controlled Medication Protocol

Some commenters expressed the strong opinion that there is a material difference between the use of doping substances to unfairly affect the performance of horses, as opposed to errors in the administration of recognized therapeutic substances. The Authority agrees that this is a vital distinction, and the Protocol recognizes the distinction in the penalty structure and other provisions throughout the Protocol.

Further detail on the meaning of ''Owner'' has been provided to take account of the varied and sometimes complex ownership structures in horseracing (Rule 3020(c)).

The term ''Responsible Person'' defined in Rule 3030 has been

simplified to make clear that the trainer of a Covered Horse is the Responsible Person for that horse. In circumstances where the horse does not have a Trainer, the Owner is the Responsible Person. The Responsible Person is personally liable for his or her Covered Horse(s). However, other Covered Persons (including veterinarians, among others) who made a relevant decision about the Covered Horse may be found to be complicit in a violation and may be liable to the same extent as the Responsible Person.

In response to comments received, the Authority removed the disciplinary provisions concerning hypodermic needles, because equivalent provisions are included in the Rule 2000 Series (Racetrack Safety Program).

Some commenters proposed increasing the sanctions applicable to repeat medication violation offenders and lengthening the period of time that such violations would remain on their ''official record.'' The limitation period and roll-off period for Controlled Medication Rule Violations has been increased from one to two years, and a multiple violation penalty points system, modelled on the ARCI system, has been added. As a consequence, in addition to any sanction received for the underlying Controlled Medication Rule Violation, a Covered Person will also receive a certain number of penalty points which accumulate over a two-year period. When the points thresholds are exceeded, additional sanctions will be imposed (in a manner similar to the points system in the driver's licensing violation system).

A number of commenters requested that Controlled Medication Substances be stratified into different classes, with individual screening limits prescribed for each category. The Authority has done so by classifying Controlled Medication Substances into Classes A to C in the Technical Document-Prohibited Substances, which supplements the Prohibited List. The sanctions in the Protocol in turn depend on the class of substance in issue.

Commenters requested clarification of the requirement that a Responsible Person make a Covered Horse available for testing ''at any time and place.'' The Protocol was clarified to specify that the Covered Horse must be available for testing at any time and place where the horse is located (*e.g.,* Racetrack, Training Facility, private facility). The Protocol was also clarified to specify that Responsible Persons shall ensure that the Covered Horse is produced for Sample collection immediately upon notification by a duly authorized Person, or, if the horse is not available at the location for Testing, within 6 hours of notification by a duly authorized Person (or if the Agency agrees to extend that time period due to extenuating circumstances, then within such extended time period). Failure to produce a Covered Horse for Sample collection within six hours (or any extended period agreed by the Agency) shall constitute a violation of Rule 3215 (evasion, or refusal or failure to submit to Sample collection). Sample collection shall ordinarily be conducted where the Covered Horse is located (*e.g.,* Racetrack, Training Facility, or private facility), unless the Agency agrees that the Covered Horse may be transported to another agreed location (*e.g.,* a nearby Racetrack).

In response to comments received, the Authority extended the period of inactivity of a Covered Horse from 12 to 18 months, after which the horse may be retired by the Authority, subject to an objection by the Owner of the horse. This change was based on the rationale that horses may suffer injuries that require a 12-month recovery period (such as tendon injuries).

The Protocol was modified to clarify that where a horse's Sample reveals the presence of more than one Controlled Medication Substance above the applicable thresholds (if any), each substance may be treated as a separate presence violation.

The Protocol was revised to clarify that Covered Persons may request clearance testing to be conducted on their Covered Horses by a Laboratory, but only if such request is authorized by the Authority in advance and paid for by the Covered Person, and provided that such samples will be treated in the same way as official Post-Race Samples, such that any violation detected may be pursued by the Agency.

Some concerns were expressed regarding how cases involving environmental contamination would be handled and publicized. The Authority has incorporated an ''Atypical Findings Policy'' as Appendix 1 to the Rule 3000 Series. The Policy allows for certain substances to be investigated first as Atypical Findings before being pursued as Adverse Analytical Findings. If further to such investigation it is determined that the positive test was the result of environmental contamination, the matter will not be pursued as an Adverse Analytical Finding, and the Atypical Finding will not be publicly disclosed.

The Authority has added provisions to the Protocol to clarify the provisions on claimed horses. Some commenters expressed the concern that testing every horse in a claiming race would be excessive. In particular, Rule 3060 provides that a claimed horse may be subject to Sample collection at a claiming race if elected (and paid for) by the claimant. If the analysis of such Sample(s) results in an Anti-Doping Rule Violation or Controlled Medication Rule Violation, the claim may be voided at the option of the claimant and the claimant shall be entitled to return of all sums paid for the claimed horse and of all expenses incurred after the date of the claim.

Commenters also expressed the opinion that use of Lasix should not be prohibited during training. The Protocol does not prohibit the use of Lasix during training (see Rule 4212(d)).

4000 Series—Prohibited List

The key change made based on comments received was the development of the ''Technical Document—Prohibited Substances,'' which supplements the Prohibited List. The Technical Document provides additional detail concerning the Prohibited Substances that fall into the general categories established in the Prohibited List, and sets forth detection times, screening limits, and thresholds for those Prohibited Substances. The Technical Document also designates certain Prohibited Substances as Specified Substances. Specified Substances are those substances that pose a higher risk of being the result of contamination, and that are therefore subject to more flexible sanctions.

Comments were also received urging that anti-ulcer medications should be permitted within 24 hours prior to a race. The ADMC considered that proposition further, including the scientific paper referenced below, which shows that the pH of gastric fluids returns to baseline 24 hours after treatment with Omeprazole (an anti-ulcer medication). Given that pH directly affects the development of ulcers, the paper supports the use of anti-ulcer medications up to 24 hours prior to Post-Time. To require a longer withdrawal interval means that the stomach lining of a horse could be vulnerable to the recrudescence of gastric ulceration.

5000 Series—Equine Testing and Investigations Standards

In addition to a number of minor revisions based on the comments received, the Authority added a section to address procedures for TCO2 testing, *i.e.,* testing blood samples for total carbon dioxide as evidence of use or administration of the Controlled Medication Method M4 (alkalinization

or use/administration of an alkalinizing agent) (see Rule 5430).

6000 Series—Equine Standards for Laboratories and Accreditation

A number of minor revisions were made based on the detailed comments received and further consultation with laboratory experts. Some duplication with ISO/IEC 17025 was also removed, in particular in section 6300.

7000 Series—Arbitration Procedures

Some commenters expressed confusion concerning the role of racing stewards in the adjudication body previously designated as the ''National Stewards Panel.'' The body is now designated as the ''Internal Adjudication Panel,'' with individual members referred to as IAP members instead of ''stewards.''

The procedure for Controlled Medication Rule Violations was developed partly in response to requests by commenters to provide for a simplified hearing process for Covered Persons charged with a violation. The procedures allow the IAP members adjudicating the case to dispense with written filings and permit the Covered Person to make an oral presentation in a hearing context. This procedure allows the adjudication process to dispense where appropriate with certain of the more formal and costly aspects of legal proceedings.

The Arbitration Procedures were also clarified to specify that hearings regarding alleged breaches of the Protocol will not be open to the media or the public, and to specify the Owners who may attend hearings involving Covered Horses when the horse is owned by multiple persons or entities.

The Arbitration Procedures were also clarified to specify that while document production requests may be permitted, discovery or other wide-ranging document requests are not permitted.

IV. Legal Authority

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

V. Effective Date

If approved by the Commission, this proposed rule will become effective January 1, 2023.

VI. 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 supporting documentation 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 *https://www.regulations.gov.*

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.'' [7] In other words, the Commission will evaluate the proposed 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.'' [8] 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 Registration 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 Practice (Part 1, Subpart D); [9] 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.'' [10] 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.'' [11]

VII. 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 November 14, 2022. Write ''HISA Anti-Doping and Medication Control'' 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 Anti-Doping and Medication Control'' 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.

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

[7] 15 U.S.C. 3053(c)(2).

[8] 15 U.S.C. 3053(e).

[9] 16 CFR 1.31; *see* Fed. Trade Comm'n, Procedures for Responding to Petitions for Rulemaking, 86 FR 59851 (Oct. 29, 2021).

[10] 16 CFR 1.31(b)(3).

[11] 15 U.S.C. 3053(e).

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 *https://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 November 14, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/siteinformation/privacypolicy.*

VIII. 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).

IX. Self-Regulatory Organization's Proposed Rule Language

1000. General Provisions

Rule 1010. Rules of Interpretation

Unless specified otherwise:

(a) words in the singular include the plural, and words in the plural include the singular;

(b) references to any ''Rule'' or ''Rule Series'' are references to the rules or rule series approved by the Commission pursuant to section 3053 of the Act;

(c) any Appendices to a Rule Series form an integral part of such Rule Series;

(d) any reference to a provision in rules, protocols, policies, standards, guidelines, or similar includes any modifications or successor provisions made or issued from time to time;

(e) any reference to legislation includes any modification or re-enactment of legislation enacted in substitution of that legislation, and any regulation or other instrument from time to time issued or made under that legislation;

(f) any term defined in this Rule 1000 Series shall supersede the definition of that term in the Rule 2000 Series;

(g) a reference to ''writing,'' ''write,'' or ''written'' includes communications transmitted by email;

(h) a reference to ''may'' means ''in the sole and absolute discretion of such person or body'';

(i) a reference to a ''day'' means any day of the week and is not limited to working days;

(j) any time limits shall begin from the day after which the relevant notification is received (or the day after the relevant notification is sent, if sent by email). Official holidays and non-working days are included in the calculation of time limits. The time limits fixed under this Protocol are respected if the communications by the parties are sent before midnight (U.S. Eastern time) on the last day on which such time limits expire. If the last day of the time limit is an official holiday or a non-business day in the state or country where the notification has been made, the time limit shall expire at the end of the first subsequent business day;

(k) a reference to a ''person'' (with no initial capital letter) means a natural person; and

(l) any words following the terms ''including,'' ''include,'' ''in particular,'' ''such as,'' ''for example,'' or any similar expression, are illustrative only, and do not limit the sense of the words, description, definition, phrase, or term preceding those terms.

Rule 1020. Definitions

Act means the Horseracing Integrity and Safety Act of 2020 (15 U.S.C. 3051–3060), as amended from time to time.

ADMC means the Anti-Doping and Medication Control Standing Committee of the Authority.

Administration means providing, supplying, supervising, facilitating, or otherwise participating in the Use or Attempted Use in a Covered Horse of a Prohibited Substance or Prohibited Method. However, this definition shall not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification.

Adverse Analytical Finding (''AAF'') means 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.

Agency means the anti-doping and controlled medication enforcement agency known as the Horseracing Integrity and Welfare Unit.

Aggravating Circumstances means circumstances involving, or actions by, a Covered Person that may justify the imposition of a period of Ineligibility or fine greater than the otherwise applicable standard sanction. Such circumstances and actions include those set forth in Rule 3227 or Rule 3327 (as applicable).

Aliquot means a portion of the Sample obtained from the Covered Horse.

Analyte means a substance, compound, or measurand that is analyzed or determined in a biological matrix using an Analytical Testing Procedure performed under controlled analytical and laboratory conditions. For anti-doping and controlled medication 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 has the same meaning as Analytical Testing Procedure.

Analytical Testing means the parts of the Doping Control or Medication Control process performed at the Laboratory, which includes Sample handling, analysis, and the reporting of results.

Analytical Testing Procedure means a Fit-for-Purpose procedure, as demonstrated through method validation, that is used to detect, identify or quantify Analytes in a

Sample in accordance with the Laboratory Standards and relevant Technical Document(s), Technical Letter(s), Technical Note(s), or Laboratory Guidelines. Unless the context otherwise requires, Analytical Testing Procedure is also referred to or known as an Analytical Method or Test Method.

Analytical Testing Restriction (''ATR'') means a restriction on a Laboratory's application of specified Analytical Testing Procedure(s) or on the analysis of a particular class(es) of Prohibited Substances or Prohibited Methods to Samples, as determined by the Agency.

Anti-Doping Rule Violation (''ADRV'') means an anti-doping rule violation under the Protocol.

Arbitral Body has the meaning given to it in the Rule 7000 Series.

Arbitration Procedures means the arbitration procedures set forth in the Rule 7000 Series.

Assistant Trainer means a person engaged in the training of Covered Horses, under the direct or indirect supervision of a Trainer.

Association Veterinarian means a Veterinarian employed by a Racetrack.

Attempt means purposely engaging in conduct that constitutes a substantial step in a course of conduct planned to culminate in the commission of an Anti-Doping Rule Violation or Controlled Medication Rule Violation; provided, however, that there shall be no Anti-Doping Rule Violation or Controlled Medication Rule Violation based solely on an Attempt to commit a violation if the Covered Person renounces the Attempt prior to it being discovered by a third party not involved in the Attempt.

Attending Veterinarian means a Veterinarian providing treatment or services to Covered Horses hired or otherwise authorized by the Trainer or Owner or his or her respective designee.

Atypical Finding means a report from a Laboratory that requires further investigation in accordance with the Atypical Findings Policy set out at Appendix 1 to the Protocol, prior to the determination of whether it is an Adverse Analytical Finding.

Atypical Findings Policy means the policy set out at Appendix 1 to the Protocol.

Authority means the Horseracing Integrity and Safety Authority designated by section 3052(a) of the Act.

Banned Method has the meaning given to it in Rule 3111.

Banned Substance has the meaning given to it in Rule 3111.

Batch means a set of Samples processed as a group.

Bias means deviation of a measured result from the expected or reference value when using the complete measurement procedure.

Billing Standards means the standards governing compensation for arbitrators and stewards under the Arbitration Procedures.

Blood Collection Officer (''BCO'') means a Veterinarian or a veterinary technician who has been authorized by the Agency (or its delegate) to collect blood Samples from a Covered Horse.

Breeder means a Person who is in the business of breeding Covered Horses.

Certified Reference Material (''CRM'') means Reference Material 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.

Certifying Scientists means personnel appointed by a Laboratory 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.

Chain of Custody means the sequence of individuals or organizations who have responsibility for the custody of a Sample from the provision of the Sample until the Sample has been delivered to the Laboratory for analysis.

Chaperone means a person authorized by the Agency (or its delegate) to carry out the responsibilities given to Chaperones in the Testing and Investigations Standards or by the DCO.

Charge Letter has the meaning given to it in (as the context requires) Rule 3248 or Rule 3348.

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

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

Code of Ethics means the Code of Ethics for Laboratories set forth at Rule 6610.

Commission means the Federal Trade Commission.

Confirmation Procedure (''CP'') means an Analytical Testing Procedure that has the purpose of confirming the presence in a Sample—or, when applicable, confirming the concentration, ratio, or score, 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.

Consequences means the penalties resulting from the occurrence of one or more violations of the Protocol, as set forth in the Rule 3000 Series. The Consequences for an Anti-Doping Rule Violation or a Controlled Medication Rule Violation may include one or more of the following:

(1) Disqualification;
(2) Ineligibility;
(3) Provisional Suspension;
(4) financial penalties; and
(5) Public Disclosure.

Contaminated Product means a product other than feed, hay, or water, that contains a Prohibited Substance that (i) is not disclosed on the product label, and (ii) a Veterinarian or Trainer would not otherwise reasonably be aware might be included in the product.

Controlled Medication Method means any method so described on the Prohibited List.

Controlled Medication Rule Violation has the meaning given to it in Rule 3311(a).

Controlled Medication Substance means any substance so described on the Prohibited List or the Technical Document—Prohibited Substances.

Corrective Action Report (''CAR'') means a report describing the Root Cause Analysis of a 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.

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 section 3054(*l*), during the period: (A) 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 (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b).

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 Person means all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses.

Decision Limit means the value of the result for a Threshold Substance in a Sample, above which an Adverse Analytical Finding shall be reported.

Designated Owner has the meaning given to it in Rule 3020(c).

Detection Time means the interval after a medication is administered during which it is detectable in a specific matrix (serum, plasma, urine, or hair) from any member(s) of a group of test horses. Detection times are determined from analysis of samples collected at specific time points following an administration of a medication to group of, potentially as few as 2, test horses. A detection time is not the same as a withdrawal time. The withdrawal time for a medication must be decided upon by a Veterinarian (in consultation with the Responsible Person) and is likely to be based on the Detection Time and an added safety margin. This margin should be determined using professional judgment and discretion to take into account the variability that could be expected to normally occur in a larger population by considering individual differences between horses, such as size, metabolism, fitness, health, or recent illness or disease. The withdrawal interval used for a medication should always be longer than its Detection Time.

Disqualification means the results of a Covered Horse in a particular Covered Horserace are invalidated, with all resulting consequences, including forfeiture of any purses and other compensation, prizes, trophies, points, and rankings associated with such Covered Horserace.

Doping Control means all steps and processes from test distribution planning through to ultimate disposition of any adjudication and review process pursuant to the Protocol and the Act involving an Anti-Doping Rule Violation and the enforcement of Consequences, including all steps and processes in between, including Testing, investigations, whereabouts program, Sample collection and handling, Laboratory analysis, Results Management, hearings and reviews, and investigations and proceedings relating to Anti-Doping Rule Violations not arising from or related to Testing or violations of Rule 3229.

Doping Control Officer (''DCO'') means an official who has been authorized by the Agency (or its delegate) to carry out the responsibilities given to DCOs in the Testing and Investigations Standards and any related Agency procedures.

EAD Notice has the meaning given to it in Rule 3245.

EAD Violations means Anti-Doping Rule Violations arising out of the Rule 3000 Series and violations of Rule 3229.

ECM Notice has the meaning given to it in Rule 3345.

ECM or Other Violations means Controlled Medication Rule Violations arising out of the Rule 3000 Series, violations of Rule 3329, or violations of Rule 3510.

Equibase means the official database for Thoroughbred horseracing.

Equine Constituencies means, collectively, Owners, Breeders, Trainers, Racetracks, Veterinarians, State Racing Commissions, and Jockeys who are engaged in the care, training, or racing of Covered Horses.

Equine Industry Representative means an organization regularly and significantly engaged in the equine industry, including organizations that represent the interests of, and whose membership consists of, Owners, Breeders, Trainers, Racetracks, Veterinarians, State Racing Commissions, or Jockeys.

Expanded Measurement Uncertainty means the multiplication of the coverage factor (q.v.) by the Measurement Uncertainty (q.v.).

External Quality Assessment Scheme (''EQAS'') means a program for quality assessment of Laboratory performance, which includes the periodic distribution of urine, blood, hair, or other samples to Laboratories and probationary laboratories by the Agency, to be analyzed for the presence or absence of Prohibited Substances 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).

Fault means any breach of duty or any lack of care appropriate to a particular situation. Factors to be taken into consideration in assessing a Covered Person's degree of Fault include (but are not limited to) the Covered Person's experience and 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 conducted appropriate due diligence, educated, supervised, and monitored Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses, and created and maintained systems to ensure compliance with the Protocol. 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 or Covered Horse only has a short time left in a career, or the timing of the horseracing calendar, would not be relevant factors to be considered in reducing the period of Ineligibility based on degree of Fault.

Fit(ness)-for-Purpose means suitable for the intended purpose and in conformity with the ISO/IEC 17025, ILAC–G7, the Laboratory Standards, and relevant Technical Document(s) and Technical Letter(s).

Further Analysis means additional analysis conducted by a Laboratory on an A Sample or a B Sample after it has reported an analytical result for that A Sample or that B Sample, save that it excludes (and, therefore, there is no limitation on a Laboratory's authority to conduct) repeat or confirmation analysis, and analysis with additional or different Analytical Methods.

IAP member means a member of the Internal Adjudication Panel.

Immediate Family Member means a spouse, domestic partner, mother, father, aunt, uncle, sibling, or child.

Ineligibility means the Covered Horse or Covered Person is barred for a specified period of time from participating in specified activities, as further particularized in the provisions of the Protocol relating to Ineligibility.

Initial Testing Procedure (''ITP'') means an Analytical Testing Procedure whose purpose is to identify those Samples that 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.

Interested Party means the Authority, the Owner of the Covered Horse, the Trainer of the Covered Horse, and the relevant State Racing Commission (provided that such State Racing Commission has entered into an agreement incorporating required confidentiality provisions).

Intermediate Precision (sw) means variation in results observed when one or more factors, such as time,

equipment, or operator, are varied within a Laboratory, and may also be referred to as inter-batch or inter-run precision.

Internal Adjudication Panel has the meaning given to it in the Rule 7000 Series. The Internal Adjudication Panel shall have the same meaning as the National Stewards Panel in any other rules approved by the Commission.

Jockey means a rider or driver of a Covered Horse in Covered Horseraces.

Laboratory means a laboratory approved by the Agency, applying Test Methods and processes to provide evidentiary data for the detection or identification of Prohibited Substances, Metabolites, Markers, or Prohibited Methods, and, if applicable, quantification of a Threshold Substance in Samples of urine, blood, hair, and other biological matrices in the context of Doping Control or Medication Control activities.

Laboratory Director means a person appointed by a Laboratory to be responsible for overseeing the professional, organizational, educational, operational, and administrative responsibilities of the Laboratory's operations in accordance with the Laboratory Standards.

Laboratory Documentation Package (''LDP'') means the physical or electronic material produced by a Laboratory upon reporting of an Adverse Analytical Finding or as requested by the Agency to support an analytical result such as an Adverse Analytical Finding or an Atypical Finding.

Laboratory Expert Group (''LabEG'') means the group of laboratory experts responsible for providing advice, recommendations, and guidance to the Agency with respect to the overall management of Laboratory accreditation, disciplinary action, re-accreditation, approval processes, and monitoring activities.

Laboratory Guidelines (''LGs'') means recommendations of Laboratory best practices that may be 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, or Prohibited Method(s), or on the application of specific Laboratory procedures.

Laboratory Internal Chain of Custody means documentation maintained within the Laboratory to record the chronological traceability of custody 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 means the Equine Standards for Laboratories and Accreditation set forth in the Rule 6000 Series.

Laboratory Supervisory Personnel means personnel appointed by a Laboratory to serve as Laboratory supervisors.

Limit of Detection (''LOD'') means the analytical parameters 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 used.

Limit of Identification (''LOI'') means 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 a Technical Document.

Limit of Quantification (''LOQ'') means the 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.

Management System refers to the Laboratory's quality system to deal with control of management system documents and records and with actions to address risk, test improvements, corrective actions, and ongoing management reviews.

Managing Owner has the meaning given to it in Rule 3020(c).

Marker means a compound, group of compounds, or biological variable(s) that indicates the Use of a Prohibited Substance or Prohibited Method.

Measurement Uncertainty (''MU'') means the 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.

Medication Control means all steps and processes from test distribution planning through to ultimate disposition of any adjudication and review process pursuant to the Protocol and the Act involving a Controlled Medication Rule Violation and to enforcement of Consequences, including all steps and processes in between, including Testing, investigations, whereabouts program, Sample collection and handling, Laboratory analysis, Results Management, hearings and reviews, and investigations and proceedings relating to Controlled Medication Rule Violations not arising from or related to Testing or violations of Rule 3329.

Metabolite means any substance produced from a Prohibited Substance by a biotransformation process.

Minimum Reporting Level means the estimated concentration of a Prohibited Substance or its Metabolite(s) or Marker(s) in a Sample below which Laboratories will not report that Sample as an Adverse Analytical Finding.

Minimum Required Performance Level (''MRPL'') means minimum analytical criterion of Laboratory technical performance established by the Agency, including the minimum concentration at which a Laboratory is expected to consistently detect and confirm a Prohibited Substance, Metabolite of a Prohibited Substance, or Marker of a Prohibited Substance or Prohibited Method in the routine daily operation of the Laboratory.

Minor means a natural person who has not reached the age of 18 years.

National Stewards Panel means the Internal Adjudication Panel.

Negative Finding means a test result from a Laboratory that, in accordance with the Laboratory Standards and any relevant Technical Document(s) and 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 Fault or Negligence means the Covered Person establishing that he or she did not know or suspect, and could not reasonably have known or suspected, even with the exercise of utmost caution, that he or she had administered to the Covered Horse (or that the Covered Horse's system otherwise contained) a Banned Substance or a Controlled Medication Substance, or that he or she had Used on the Covered Horse a Banned Method or a Controlled Medication Method, or

otherwise committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation. For any violation of Rule 3212 or Rule 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Fault or Negligence.

No Significant Fault or Negligence means the Covered Person establishing that his or her fault or negligence, when viewed in the totality of the circumstances and taking into account the criteria for No Fault or Negligence, was not significant in relationship to the Anti-Doping Rule Violation or Controlled Medication Rule Violation in question. For any violation of Rule 3212 or 3312, the Covered Person must also establish how the Prohibited Substance entered the Covered Horse's system in order to establish No Significant Fault or Negligence.

Nominated Person means a person nominated by a Responsible Person at the time of notification or through a whereabouts filing to assist, consent to, and witness Sample collection from a Covered Horse. If the Responsible Person is not present to nominate a person, or the designated Nominated Person is not present or willing to assist with Sample collection, anyone employed by the Responsible Person or Owner at the stable where the Covered Horse is located 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, BCO, or Chaperone access to the Covered Horse shall be the Nominated Person for that Sample collection. In each case, the Nominated Person shall be 18 years or older.

Non-Threshold Substance means a Prohibited Substance for which the identification, in compliance with any applicable Technical Document(s), constitutes an Adverse Analytical Finding.

Owner means a person who holds an ownership interest in one or more Covered Horses.

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

Possession means actual, physical possession, or constructive possession (which shall be found only if the Covered Person has exclusive control or intends to exercise exclusive control over the Prohibited Substance or Prohibited Method or the premises in which a Prohibited Substance or Prohibited Method exists). If the Covered 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 Covered 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 or Controlled Medication Rule violation based solely on Possession if, prior to receiving notification of any kind of any violation, the Covered Person has taken concrete action demonstrating that the Covered Person never intended to have possession and has renounced possession by explicitly declaring it to the Agency. Notwithstanding anything to the contrary in this definition, the act of purchasing (including by any electronic or other means) a Banned Substance or Banned Method constitutes Possession by the Covered Person who makes the purchase, whether or not the Banned Substance or Banned Method purchased is ever delivered to the Covered Person.

Post-Race Sample means a Sample collected by or on behalf of the Agency from a Covered Horse where notification of such Sample collection takes place no more than 1 hour after the end of a Covered Horserace in which a Covered Horse participates or is entered, or the end of a Vets' List Workout in which a Covered Horse participates. All Banned Substances and all Controlled Medication Substances are prohibited from being present in a Post-Race Sample.

Post-Time means the start time of a Covered Horserace in which a Covered Horse participates or is entered, or the start time of a Vets' List Workout in which a Covered Horse participates.

Post-Work Sample means a Sample collected by or on behalf of the Agency from a Covered Horse where notification of such Sample collection takes place no more than 1 hour after the end of a Timed and Reported Workout. All Banned Substances and any Controlled Medication Substances specifically identified on the Prohibited List as prohibited during Timed and Reported Workouts are prohibited from being present in a Post-Work Sample.

Presumptive Adverse Analytical Finding (''PAAF'') means 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.

Program means the anti-doping and medication control program established under section 3055(a) of the Act.

Program Effective Date means January 1, 2023.

Prohibited List means the list identifying Prohibited Substances and Prohibited Methods set forth in the Rule 4000 Series.

Prohibited Method means any method so described on the Prohibited List.

Prohibited Substance means any substance or class of substances so described on the Prohibited List or the Technical Document–Prohibited Substances.

Protocol means the Rule 3000 Series (Equine Anti-Doping and Controlled Medication Protocol), as amended from time to time.

Provisional Hearing means an expedited abbreviated hearing to resolve a challenge to a Provisional Suspension, occurring prior to the adjudication of the violation in issue.

Provisional Suspension means the Covered Horse or Covered Person is barred temporarily from participating in any Timed and Reported Workout or Covered Horserace in accordance with Rules 3229 or 3329 (as applicable).

Public Disclosure means the dissemination or distribution of information by the Authority or the Agency to the general public.

Quality Manager means the staff member appointed by a Laboratory to perform that role in accordance with the Laboratory Standards.

Race Day means the period commencing at 12:01 a.m. on the day of a Vets' List Workout or Covered Horserace and ending (i) 1 hour after the end of such Vets' List Workout or Covered Horserace or (ii) at the end of any Sample Collection Session conducted at that Vets' List Workout or Covered Horserace when the Covered Horse is released from the Test Barn, whichever is later.

Race Organizer means any Person that arranges, organizes, and has administrative responsibility for a Covered Horserace.

Race Period means the period:

(a) commencing 48 hours prior to the Post-Time of either (i) any Vets' List Workout in which the Covered Horse participates or (ii) any Covered Horserace that the Covered Horse has been entered in, whether or not the Covered Horse actually starts; and

(b) ending (i) 1 hour after the end of such Vets' List Workout or Covered Horserace or (ii) at the end of any Sample collection process conducted at that Vets' List Workout or Covered Horserace when the Covered Horse is released from the Test Barn, whichever is later.

However, the Prohibited List may specify a Race Period that is shorter or longer in duration than the above period for certain Controlled Medication

Substances or Controlled Medication Methods.

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

Racetrack Safety Program means the program set forth in Rule 2000 Series, established pursuant to section 3056(a) of the Act.

Reference Collection (''RC'') means 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'') means a Reference Substance or Reference Standard that 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.

Regulatory Veterinarian means a Veterinarian who is employed, contracted, or appointed by a State Racing Commission, Racetrack, the Authority, or the Agency to monitor the health and welfare of Covered Horses, in addition to any other duties assigned to him or her by the Authority or the Agency.

Repeatability (sr) means 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) means 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 has the meaning given to it in Rule 3030.

Results Management means the process encompassing the timeframe from provision of an EAD Notice or ECM Notice through the charge until the final resolution of the matter, including the end of any adjudication and review process pursuant to the Protocol and the Act.

Revocation means the permanent withdrawal of a Laboratory's Equine Analytical Laboratory accreditation by the Agency.

Risk Assessment means the assessment of risk of doping and controlled medication misuse conducted by the Agency and used to effectively conduct test distribution planning or Target Testing.

RMTC has the meaning given to it in Rule 6070(a).

Root Cause Analysis (''RCA'') means an investigation to identify one or more fundamental causes 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.

Sample means any biological material collected for the purposes of Doping Control or Medication Control, including urine, blood, and hair.

Sample Collection Equipment means A and B bottles, kits, containers, collection vessels, tubes, or other apparatus used to collect, hold, or store a Sample at any time during or after a Sample Collection Session.

Sample Collection Personnel means all qualified officials authorized by the Agency to carry out or assist with duties during Doping Control or Medication Control, including, but not limited to, Blood Collection Officers, Doping Control Officers, and Chaperones. An individual may be authorized by the Agency to carry out one or more roles during Doping Control or Medication Control.

Sample Collection Session means all of the sequential activities that directly involve the collection of a Sample from a 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 is discharged from Sample collection obligations.

Screening Limit means a concentration to be used by Laboratories when screening for certain Non-Threshold Substances during the Initial Testing Procedure, below which a Laboratory will not pursue the possible presence of a Prohibited Substance. When the concentration of an Analyte subject to a Screening Limit exceeds the Screening Limit as determined by the Initial Testing Procedure, qualitative confirmatory analysis by mass spectrometry Confirmation Procedure is required to confirm the presence or absence of the Prohibited Substance. Quantification is not required. A Screening Limit is not a Limit of Detection, a Limit of Identification, or a Limit of Quantification.

Selectivity means the ability of the Analytical Testing Procedure to detect or identify (as applicable) the substance of interest in the Sample.

Specified Substance has the meaning given to it in Rule 3111(c).

Stacking Violation has the meaning given to it in Rule 3312(e).

Stakes Race means any race so designated by the Racetrack at which such race is run, including, without limitation, the races the Breeders' Cup World Championships comprises and the races designated as graded stakes by the American Graded Stakes Committee of the Thoroughbred Owners and Breeders Association.

Standard Operating Procedure means a document setting out prescribed methods or procedures to be followed when performing certain routine operations.

Standards means the Testing and Investigations Standards and the Laboratory Standards. Compliance with a Standard (as opposed to another alternative standard, practice, or procedure) shall be sufficient to conclude that the procedures addressed by the Standard were performed properly. Standards shall include any Technical Documents issued pursuant to the Standards.

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

Substantial Assistance means, for purposes of Rule 3226(a) and Rule 3326(a), a Covered Person providing the following assistance:

(1) fully disclosing in a signed written statement or recorded interview all information the Covered Person possesses in relation to violations of the Protocol; and

(2) fully cooperating with the investigation and adjudication of any case or matter related to that information, including, for example, by providing an affidavit and presenting testimony at a hearing if requested to do so by the 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.

Tamper Evident means to have one or more indicators or barriers to entry included with or incorporated into the Sample Collection Equipment, which, if breached, missing, or otherwise compromised, can provide visible evidence that Tampering or Attempted Tampering of Sample Collection Equipment has occurred.

Tampering means intentional conduct that subverts the Doping Control or Medication Control process, but that would not otherwise be included in the definition of Prohibited Methods. Tampering includes 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 the Agency (or a committee or adjudication body), procuring false testimony from witnesses, committing any other fraudulent act upon the Agency (or committee 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 or Medication Control. However, this definition shall not include the actions of bona fide veterinary personnel involving a Controlled Medication Substance or Controlled Medication Method used for genuine and legal therapeutic purposes or other acceptable justification.

Target Testing means selection of specific Covered Horses for Sample collection based on criteria set forth in the Testing and Investigations Standards.

Technical Document (''TD'') means a document adopted and published by the Authority from time to time containing requirements or guidance on specific anti-doping or medication control topics.

Technical Letter (''TL'') means a document published containing mandatory technical requirements provided by the Agency from time to time to address particular issues on the analysis, interpretation, and reporting of specific Prohibited Substance(s), Metabolites, Markers, or Prohibited Method(s), or on the application of specific Laboratory procedures.

Technical Note (''TN'') means technical guidance provided by the Agency to Laboratories on the performance of specific Laboratory methods or procedures.

Test Barn means the location where Sample collection is conducted on Race Day.

Test Barn Veterinarian means a Veterinarian who is employed, contracted, or appointed by a State Racing Commission, Racetrack, the Authority, or the Agency to monitor the health and welfare of Covered Horses subject to Sample collection in the Test Barn.

Testing means the parts of the Doping Control or Medication Control process involving Sample collection, Sample handling, and Sample transport to the Laboratory.

Testing and Investigations Standards means the Equine Testing and Investigations Standards set forth in the Rule 5000 Series.

Test Method has the same meaning as Analytical Testing Procedure.

Thoroughbred means a horse that is registered in The American Stud Book or in a foreign stud book approved by the Jockey Club or the International Stud Book Committee.

Threshold means 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 may only be adopted for (i) substances endogenous to the horse or (ii) substances arising from plants traditionally grazed or harvested as equine feed.

Threshold Substance means a Prohibited Substance, or Metabolite or Marker of a Prohibited Substance, for which the identification and quantitative determination, including, for example, concentration, ratio, or score, in excess of a pre-determined Decision Limit, or, when applicable, the establishment of an exogenous origin, constitutes an Adverse Analytical Finding.

Timed and Reported Workout means an officially timed and published running of a Thoroughbred horse over a predetermined distance that is not a horserace, as reported by Equibase or any official supplier of racing information and statistics recognized by the Authority. Official timed workouts shall have the same meaning as Timed and Reported Workouts. Any official timed workout by a Thoroughbred horse in any other jurisdiction shall be deemed a Timed and Reported Workout upon the earliest to occur of the following: (i) the horse is brought to the United States for purposes of participating in any Covered Horserace; or (ii) the horse is nominated for a Covered Horserace.

Trafficking means a Covered Person selling, giving, transporting, sending, delivering, or distributing by any means a Banned Substance or Banned Method to any other Person, or Possessing a Banned Substance or Banned Method for any such purpose; provided, however, that Trafficking shall not include the actions of Veterinarians or other licensed medical personnel involving a Prohibited Substance used for genuine and legal therapeutic purposes or other acceptable justification.

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 Timed and Reported Workouts.

Use means the utilization, application, ingestion, injection, or consumption by any means whatsoever of any Prohibited Substance or Prohibited Method in relation to a Covered Horse.

Veterinarian means a licensed veterinarian who provides veterinary services to Covered Horses.

Veterinarians' List has the meaning given to it in Rule 2000 Series (Racetrack Safety Program).

Vets' List Workout means an officially timed running of a Covered Horse over a predetermined distance that is not a Covered Horserace but is overseen by a Regulatory Veterinarian or Racetrack steward.

Whereabouts Failure means a failure by the Responsible Person to do any of the following: (i) provide notice to the Agency that his or her Covered Horse has been moved from a Racetrack or Training Facility to a private facility (*i.e.,* a facility not under the jurisdiction of the Authority/Agency) before such move occurs; (ii) provide whereabouts information about his or her Covered Horse(s) upon request by the Agency; (iii) provide sufficient information about the Covered Horse's whereabouts to enable the Agency to Test the Covered Horse at any time; or (iv) update any whereabouts information provided to the Agency if it changes.

Without Prejudice Agreement means a written agreement between the Agency and a Covered Person that allows the Covered Person to provide information to the Agency in a defined time-limited setting with the understanding that, if an agreement for Substantial Assistance or a case resolution agreement is not finalized, the information provided by either party may not be used by the other party in any Results Management proceeding under this Protocol. Such an agreement shall not preclude the parties from using any information or evidence gathered from any source.

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 section 3054(*l*) of the Act of the horse's breed governing organization or the applicable State Racing Commission.

3000. Equine Anti-Doping and Controlled Medication Protocol

3000. General Provisions

Rule 3010. Introduction

(a) The Horseracing Integrity and Safety Act of 2020 (''Act'') mandates and empowers the Horseracing Integrity and Safety Authority (''Authority'') to establish a uniform anti-doping and controlled medication program to improve the integrity and safety of horseracing in the United States (''Program'').

(b) This Equine Anti-Doping and Controlled Medication Protocol (''Protocol'') has been developed and issued by the Authority as part of that mandate. It contains or incorporates by reference rules, standards, and procedures to improve and protect the integrity and safety of horseracing in the United States by deterring and penalizing the improper administration or application of Prohibited Substances and Prohibited Methods to Covered Horses. The Protocol is split into five chapters:

(1) the purpose, scope, and organization of the Protocol;

(2) the Prohibited List, rules of proof, and testing and investigations;

(3) the Equine Anti-Doping Rules;

(4) the Equine Controlled Medication Rules; and

(5) other violations and general procedure/administration.

(c) The Protocol has intentionally divided the regulation of Anti-Doping Rule Violations and Controlled Medication Rule Violations into separate chapters to reflect the Authority's view that the treatment of such violations should be separate and distinct from each other. Anti-Doping Rule Violations involve Banned Substances or Banned Methods, which are substances/methods that should never be in a horse's system or used on a horse as they serve no legitimate treatment purpose. Conversely, Controlled Medication Rule Violations involve Controlled Medication Substances or Controlled Medication Methods, which are substances/methods that have been determined to have appropriate and therapeutic purposes, and so may be used outside the Race Period, except as otherwise provided in the Prohibited List. For the avoidance of doubt, the Protocol does not regulate the use of drugs or medications by human participants in Covered Horseraces.

(d) The Protocol reflects and implements the following principles set out in section 3055(b) of the Act that:

(1) Covered Horses should compete only when they are free from the influence of medications, other foreign substances, and treatment methods that affect their performance;

(2) Covered Horses that are injured or unsound should not train or participate in Covered Horseraces, and that 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 Horseraces should be uniform and uniformly administered throughout the United States;

(4) to the extent consistent with the Act, 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 upon a veterinary 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 that a Covered Horse receives should be the minimum necessary to address the diagnosed health concerns identified during the veterinary examination and diagnostic process; and

(7) the welfare of Covered Horses, the integrity of the sport of horseracing, and the confidence of its stakeholders (including the betting public) require full disclosure to regulatory authorities regarding the administration of medications and treatments to Covered Horses.

(e) The Protocol will be implemented and enforced on behalf of the Authority by:

(1) an anti-doping and controlled medication enforcement agency known as the Horseracing Integrity and Welfare Unit (''Agency''); and

(2) where agreed in accordance with 3060 of the Act, by State Racing Commissions acting under the delegated authority of the Authority or the Agency (and references to the Authority or the Agency in the Protocol will be deemed to encompass such commissions as the context requires, subject to and consistent with the scope of their delegated authority).

(f) In accordance with section 3054(b) of the Act, the rules of the Authority promulgated in accordance with the Act shall preempt any provision of state law or regulation with respect to matters within the jurisdiction of the Authority under the Act. Among other things, the Protocol:

(1) identifies the conduct that will constitute an Anti-Doping Rule Violation (Rules 3211 to 3216), a Controlled Medication Rule Violation (Rules 3311 to 3315), or a related violation (Rules 3229, 3329, and 3510);

(2) establishes evidentiary and other rules for proving violations of the Protocol (Rules 3121 to 3122);

(3) provides for the creation, maintenance, and updating of a Prohibited List and related Technical Document that identify Prohibited Substances and Prohibited Methods (Rules 3111 to 3113);

(4) empowers the Agency to perform and manage test distribution planning and Testing of Covered Horses both in and out of competition, in accordance with the Testing and Investigations Standards (Rule 3133);

(5) empowers the Agency to gather intelligence and investigate potential violations of the Protocol, in accordance with the Testing and Investigations Standards, which incorporate uniform rules and procedures in accordance with section 3054(c) of the Act (Rule 3133);

(6) empowers the Agency to accredit testing laboratories in accordance with the Laboratory Standards and to monitor, test, and audit approved Laboratories to ensure continuing compliance with the Laboratory Standards; and provides for all samples collected pursuant to the Protocol to be analyzed at approved Laboratories in accordance with the Laboratory Standards or by other laboratories, such as international laboratories accredited by the International Federation of Horseracing Authorities, in accordance with Rule 3136(d) (Rule 3136);

(7) sets out uniform rules and procedures for the Agency's management of the results of testing and investigations, and for its prosecution of any charges that Covered Persons have violated the Protocol, including incorporating the Arbitration Procedures to ensure the fair adjudication of those charges;

(8) sets out the sanctions that may be applied in case of violations of the Protocol, including, but not limited to, Disqualification of results, forfeiture of prizes and purses, fines, payment of costs, periods of Ineligibility for Covered Horses or Covered Persons (including additional periods of Ineligibility for repeat offenders), and Public Disclosure (sections 3220 and 3320); and requires the Authority,

Racetracks, Race Organizers, Training Facilities, all Covered Persons, and all other relevant Persons to recognize, respect, enforce, and give full force and effect to final decisions issued under the Protocol within their respective spheres of authority (Rule 3710);

(9) regulates the public reporting and disclosure of cases, and permits and facilitates statistical reporting to the Authority and to the U.S. Congress, the Commission, State Racing Commissions, and other Federal or State governmental bodies or agencies having jurisdiction over the sport of horseracing in the United States (section 3600); and

(10) empowers the Agency to undertake and commission education and research activities designed to advance the integrity and safety of horseracing in the United States (Rule 3810).

(g) The Protocol comes into force on the Program Effective Date and will apply in full as from that date. In accordance with section 3054(k)(1) of the Act, the Protocol only has prospective effect, *i.e.,* it does not apply to, and does not give the Authority or Agency authority to investigate, prosecute, adjudicate, or penalize conduct that occurred before the Program Effective Date (Rule 3080).

(h) The Protocol incorporates by reference the supporting rules and documents approved by the Commission and issued by the Authority, including Rule 1000 Series (General Provisions), Rule 2000 Series (Racetrack Safety Program), Rule 4000 Series (Prohibited List), Rule 5000 Series (Testing and Investigations Standards), Rule 6000 Series (Laboratory Standards), Rule 7000 Series (Arbitration Procedures), Rule 8000 Series (Enforcement Rule), Rule 8500 Series (Methodology for Determining Assessments), and Rule 9000 Series (Registration of Covered Persons and Covered Horses).

(i) In accordance with section 3055(c)(4) of the Act, the Agency may develop further rules, protocols, policies, and guidelines for approval by the Authority to support the implementation of the Protocol. These materials will be developed in consultation with the Anti-Doping and Medication Control Standing Committee (ADMC) of the Authority and will be consistent with international best practices.

(j) Nothing in the Protocol or in any of its associated rules, protocols, policies, and guidelines:

(1) is intended to constrain or limit in any way the powers of the Authority or the Agency under the Act; or

(2) shall be interpreted or applied in a manner that has the effect of constraining or limiting those powers in any way.

(k) Unless specified otherwise, words and terms in the Protocol that are capitalized are defined terms that have the meaning given to them in Rule 1020.

(l) The rules of interpretation included at Rule 1010 and Rule 3070 shall be used as an aid to interpretation of the Protocol.

Rule 3020. Application

(a) The Protocol applies to and is binding on:

(1) 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 (each, a Covered Horserace);

(2) 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 section 3054(*l*), during the period: (A) 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 (B) ending on the date on which the horse is deemed retired pursuant to Rule 3050(b) (each, a Covered Horse); and

(3) the following persons (each, a Covered Person): all Trainers, Owners, Breeders, Jockeys, Racetracks, Veterinarians, Persons licensed by a State Racing Commission, and the agents, assigns, and employees of such Persons; any other Persons required to be registered with the Authority; and any other horse support personnel who are engaged in the care, treatment, training, or racing of Covered Horses.

(b) Pursuant to section 3054 of the Act, Covered Persons must register with the Authority. However, they are bound by the Protocol by undertaking the activity (or activities) that make(s) them a Covered Person, whether or not they register with the Authority.

(c) Owners. Covered Horses may be owned by a sole individual, multiple individuals, or one or more entities. As a consequence of the various ownership structures and property interests of Covered Horses, it is necessary to identify which Person shall be responsible as the Owner for purposes of registration, communication, personal liability, and other requirements under the Protocol and related rules. Accordingly:

(1) For purposes of mandatory registration with the Authority, any Covered Person who owns a 5% or greater ownership or property interest in a Covered Horse shall register with the Authority as an Owner.

(2) The following person shall be responsible as the Owner for any communication, notification, and reporting requirements under the Protocol:

(i) if the Covered Horse is owned by one individual, that individual; or

(ii) if the Covered Horse is owned by more than one individual or by a partnership, corporation, limited liability company, syndicate, or other association or entity, the individual designated in the Authority's database as the representative for the other owners of the Covered Horse authorized to receive communications or notifications and fulfill any reporting requirements on their behalf in respect of the Covered Horse (Designated Owner).

(3) If Rule 3030 makes the Owner the Responsible Person for a Covered Horse, that shall mean that the following person is personally liable for violations involving that Covered Horse:

(i) if the Covered Horse is owned by one individual, that individual; or

(ii) if the Covered Horse is owned by more than one individual or by a partnership, corporation, limited liability company, syndicate, or other association or entity, the individual who manages the Covered Horse as a matter of fact (Managing Owner). If an individual owns more than a 50% stake in a Covered Horse or where the entity that owns the Covered Horse has designated an individual with an ownership interest in the Covered Horse as the individual who will be personally liable under the Protocol as the Owner of the Covered Horse, that individual will be presumed to be the Managing Owner. If an individual with an ownership or property interest in the Covered Horse who is not the Managing Owner makes a relevant decision about the Covered Horse that leads to a violation of the Protocol, that person shall be jointly and severally liable with the Managing Owner for such decision as an Owner of the Covered Horse.

(4) Only the following persons may attend hearings under the Protocol as the Owner of the Covered Horse, unless otherwise agreed by the hearing panel:

(i) if the Covered Horse is owned by one individual, that individual; or

(ii) if the Covered Horse is owned by more than one individual or by a partnership, corporation, limited liability company, syndicate, or other association or entity, the Designated Owner or Managing Owner.

(5) Unless the context requires otherwise, the individual owner or Managing Owner of the Covered Horse (as applicable) shall be responsible for discharging any other requirements imposed on an Owner under the Protocol or related rules.

Rule 3030. Responsible Persons

(a) ''Responsible Person'' means the Trainer of the Covered Horse. If the Covered Horse does not have a Trainer, the Responsible Person shall be the Owner of the Covered Horse. The Responsible Person shall be personally liable for his or her Covered Horse(s) as set out under the Protocol. Other Covered Persons who make a relevant decision about the Covered Horse may also be liable depending on the facts and circumstances.

(b) If a Covered Horse is claimed in a Claiming Race, the person designated as the Responsible Person prior to that Claiming Race shall be liable for any violation resulting from a Sample collected on Race Day. The person who claims the Covered Horse in the Claiming Race shall not be liable for such violation, unless he or she was complicit in the violation.

(c) The Responsible Person shall register their designation as the Responsible Person for a Covered Horse with the Authority and shall keep such designation and registration up-to-date. Any transfer of the Responsible Person designation to another Covered Person shall be done with the Authority in accordance with its procedures prior to the effective date of the transfer, except that if a Covered Horse is claimed in a Claiming Race, the transfer shall be done on the day of the Claiming Race.

(d) The Responsible Person for a Covered Horse shall be the sole representative for the interests of that Covered Horse in any matter arising under the Protocol. The Owner (if not the Responsible Person) may attend any hearing concerning a violation of the Protocol involving his or her Covered Horse(s) in accordance with the Arbitration Procedures.

Rule 3040. Core responsibilities of Covered Persons

(a) Responsibilities of All Covered Persons

It is the personal responsibility of each Covered Person:

(1) to be knowledgeable of and to comply with the Protocol and related rules at all times. All Covered Persons shall be bound by the Protocol and related rules, 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 Protocol and related rules and all revisions thereto;

(2) to cooperate promptly and completely with the Authority and the Agency in the exercise of their respective powers under the Act and the Protocol and related rules, including:

(i) in relation to the Testing program and in relation to the investigation of potential violations of the Protocol;

(ii) by providing complete and accurate information to the Authority and the Agency in all interactions and filings; and

(iii) on request by the Agency:

(A) making available for inspection any facility, office, stall, or equipment or other relevant location that is used in the care, treatment, training, or racing of Covered Horses, or any feed, medicine, or other item given to Covered Horses;

(B) submitting to under-oath transcribed interviews about his or her dealings with or in relation to Covered Horses;

(C) providing immediate and unfettered access to any and all data, documents, and records used in the care, treatment, training or racing of any Covered Horse (including, but not limited to, data, documents and records existing in electronic form, *e.g.,* on computers, mobile phones, or other devices); and

(D) permitting the Agency to review or make and take away copies of any such data, documents, or records for analysis, investigation, and potential use as evidence of a violation of the Protocol by a Covered Person;

Failure to cooperate promptly and completely with the Agency may constitute a violation pursuant to Rule 3510(b); and

(3) not to engage in offensive conduct towards any Sample Collection Personnel or any representative of the Agency or the Authority (including engaging in improper, insulting, or obstructive conduct, or recording any Sample Collection Session contrary to Rule 5410). Failure to comply may constitute a violation pursuant to Rule 3510(a) or Tampering or Attempted Tampering, depending on the circumstances of the case.

(b) Additional Responsibilities of Responsible Persons

In addition to the duties under Rule 3040(a), it is the personal responsibility of each Responsible Person:

(1) to ensure that Covered Horses for which he or she is the Responsible Person are made available for Sample collection at any time and any place where they are located (*e.g.,* Racetrack, Training Facility, private facility) upon request by the Agency (or its delegate). In particular, without limiting the generality of the foregoing:

(i) The Responsible Person shall ensure that the Covered Horse is produced for Sample collection immediately upon notification by a duly authorized person in accordance with the Agency's procedures if the Covered Horse is present at the location where notification is attempted. If the Covered Horse is present at the location where notification is attempted, failure to produce a Covered Horse immediately upon valid notification shall constitute an Anti-Doping Rule Violation under Rule 3215.

(ii) If the Covered Horse is not present at the location where notification is attempted (including due to a Whereabouts Failure), the Responsible Person shall ensure that the Covered Horse is produced for Sample collection within 6 hours of notification by a duly authorized Person in accordance with the Agency's procedures, except that the Agency may extend the 6-hour period if it determines that extenuating circumstances justify doing so. If the Covered Horse is not present at the location where notification is attempted or if a Covered Horse cannot be located by the Agency, failure to produce a Covered Horse for Sample collection within 6 hours (or any extended period agreed by the Agency) of valid notification period shall constitute an Anti-Doping Rule Violation under Rule 3215.

(2) to either be present during a Sample collection involving his or her Covered Horse and comply with all Sample collection procedure requirements, or (if not present) to ensure that a Nominated Person who is 18 years or older is present to represent him or her and complies with all Sample collection procedure requirements;

(3) to ensure that treatments and medications administered to his or her Covered Horses:

(i) are administered only on the advice of a Veterinarian or (if a prescription is not required) following sufficient due diligence regarding the treatment or medication;

(ii) are not administered in a manner detrimental or contrary to horse welfare;

(iii) are the minimum necessary to address the diagnosed health concerns identified during the veterinary examination and diagnostic process;

(iv) do not contain a Banned Substance or involve a Banned Method; and

(v) do not otherwise violate the Protocol;

(4) to inform all Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses of their respective obligations under the Protocol (including, in particular, those specified in Rule 3040(a));

(5) to adequately supervise all Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in any way with the care, treatment, training, or racing of his or her Covered Horses, including by (without limitation):

(i) conducting appropriate due diligence in the hiring process before engaging their services;

(ii) clearly communicating to such Persons that compliance with the Protocol is a condition of employment or continuing engagement in the care, treatment, training, or racing of his or her Covered Horses;

(iii) creating and maintaining systems to ensure that those Persons comply with the Protocol; and

(iv) adequately monitoring and overseeing the services provided by those Persons in relation to the care, treatment, training, or racing of his or her Covered Horses;

(6) to bear strict liability for any violations of the Protocol by such Covered Persons (including Veterinarians), employees, personnel, agents, and other Persons involved in the care, treatment, training, or racing of his or her Covered Horses;

(7) to file and update as necessary with the Authority information identifying what Covered Horses he or she is the Responsible Person for;

(8) to maintain accurate, complete, and up-to-date treatment records (including, without limitation, records of medical, therapeutic, and surgical treatments and procedures, including diagnostics) of his or her Covered Horses in an electronic or other form specified by the Agency, and to provide the Agency with access to those records upon request and without delay so that it may inspect and make and retain copies of them for purposes of monitoring and ensuring compliance with the requirements of the Protocol. The records must include the details required under Rule 2251(b). The Responsible Person must retain copies of such treatment records for a period of no less than 3 years, although the Responsible Person is advised to retain them for the duration of the limitation periods under Rule 3090;

(9) at the time of registering a horse with the Authority and prior to such horse competing in any Timed and Reported Workout or Covered Horserace, the Responsible Person shall declare in writing to the Agency all administrations of Banned Substances and Banned Methods to the horse since the Responsible Person first owned the horse (or, if not the Owner, since the Owner at the time of registration first owned the horse) or since the Program Effective date, whichever is earlier. On request by the Agency, the Responsible Person shall provide any related treatment records for the horse during that period. If a Banned Substance or Banned Method has been administered in that period, the Agency may impose a stand down period for the horse of up to the period of Ineligibility that would be applicable for the relevant Banned Substance or Banned Method and require that (at the Responsible Person's cost) the Covered Horse provide one or more negative Samples before subsequently being eligible to participate in a Timed and Reported Workout or a Covered Horserace. Failure by a Responsible Person to comply with this Rule 3040(b)(9) may constitute a violation of Rule 3510(b);

(10) if any Covered Horse is moved from a Racetrack or Training Facility to a private facility (*i.e.,* a facility not under the jurisdiction of the Authority or the Agency), the Responsible Person shall provide sufficient information about the Covered Horse's whereabouts so that the Agency remains able to collect Samples from the Covered Horse at any time. The Responsible Person shall also provide any further information about the whereabouts of a Covered Horse that is specifically requested by the Agency. Failure to do so may constitute a violation of Rule 3510(d);

(11) to notify the Authority in writing within 7 days of becoming aware that any of his or her Covered Horses:

(i) is pregnant;

(ii) was pregnant but has foaled or is no longer pregnant;

(iii) has been castrated or hemicastrated (including chemical castration or immunocastration); or

(iv) has suffered a fatal condition.

In each case, the Responsible Person shall state the name of the Covered Horse, the date of the event triggering the notice, and (for paragraph (iv) above) a summary explanation regarding the cause of the fatal condition.

(c) Additional Responsibilities of Owners

In addition to the duties under Rule 3040(a):

(1) each person with a 5% percent or greater ownership or property interest in a Covered Horse shall register with the Authority as an Owner of the Covered Horse, and ensure that any transfer of ownership is registered with the Authority in accordance with its procedures; and

(2) if a Covered Horse is owned by multiple Owners, they shall ensure that the Agency is notified in writing of one Designated Owner authorized to receive communications and notifications and fulfil any reporting requirements on their behalf.

(d) Additional Responsibilities of Attending Veterinarians

In addition to the duties under Rule 3040(a), and the further duties and requirements imposed under the Rule 2000 Series (Racetrack Safety Program), it is the personal responsibility of each Attending Veterinarian to act in strict compliance with the Protocol and keep updated treatment records (including, without limitation, records of medical, therapeutic, and surgical treatments and procedures, including diagnostics) in an electronic database designated by the Agency or in any other form designated by the Agency and provide access to the Agency upon request and without delay to or copies of such treatment records. The records must include the details required under Rule 2251(b) and must be submitted in an electronic format designated by the Authority within the deadline specified in that same provision. Attending Veterinarians must retain copies of such treatment records for a period of no less than 3 years, or for the retention period required by the relevant state veterinary practice act, whichever is longer.

Rule 3050. Retirement and Equine Fatalities

(a) Covered Persons.

(1) Each Responsible Person who wishes to no longer be bound by the Protocol shall give written notice to the Authority of his or her retirement from the position that made him or her a Responsible Person. In each case, the Responsible Person shall be deemed to have retired (and to be no longer subject to the Protocol) on the later of (i) the date given in the written notice of retirement and (ii) the date the notice is received.

(2) Any other Covered Person will continue to be bound by and required to comply with the Protocol and related rules unless and until he or she unregisters with the Authority.

(3) If a Covered Person ceases to be subject to the Protocol while the Agency is conducting a Results Management process in respect of that person, the Agency retains jurisdiction to complete

its Results Management process. If a Covered Person retires or ceases to be subject to the Protocol before any Results Management process has begun, and the Agency had jurisdiction over the Covered Person at the time the Anti-Doping Rule Violation or Controlled Medication Rule Violation was committed, the Agency retains jurisdiction to conduct Results Management in respect of that violation.

(4) If a Covered Person retires while subject to a period of Ineligibility, he or she must give written notice of such retirement to the Authority. The Covered Person may not return to the sport (*i.e.,* carry out any of the activities prohibited during the period of Ineligibility pursuant to Rules 3229 and 3329) unless the Covered Person has given 4 months' prior written notice (or notice equivalent to the period of Ineligibility remaining as of the date the Covered Person retired, if that period was longer than 4 months) to the Authority of his or her intent to return to the sport.

(5) The Agency may forward notifications of retirement of Covered Persons to Interested Parties or other Persons with a need to know.

(b) Covered Horses.

(1) If an Owner wishes to retire a Covered Horse such that it is no longer made available for Testing, the Owner must provide written notice of such retirement to the Agency, in accordance with its procedures.

(2) A Covered Horse that has been retired in accordance with the previous clause may not participate in a Timed and Reported Workout or be entered in a Covered Horserace until the Covered Horse has been made available for Testing at least 4 months prior to notice being given to the Agency (in accordance with its procedures) of the intention to unretire the Covered Horse.

(3) If a Covered Horse is retired from horseracing or suffers a fatal condition while the Agency is conducting a Results Management process in respect of it, the Agency retains jurisdiction to complete its Results Management process. If a Covered Horse is retired or suffers a fatal condition before any Results Management process has begun, and the Agency had jurisdiction over the Covered Horse at the time the Anti-Doping Rule Violation or Controlled Medication Rule Violation was committed, the Agency retains jurisdiction to conduct Results Management in respect of that violation. If a Covered Horse suffers a fatal condition, the Agency retains Testing authority over that horse in accordance with Rule 3132(d).

(4) 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 wishes that horse to return to participation in Covered Horseraces or Timed and Reported Workouts, the Owner must first provide the Agency with written notice and make the Covered Horse available for Testing for at least 4 months prior to such participation or for the remainder of the Covered Horse's period of Ineligibility, whichever is longer.

(5) In order to manage the number of Covered Horses registered with the Authority, the Agency may retire a Covered Horse based on inactivity (*i.e.,* where the Covered Horse does not participate in a Timed and Reported Workout or Covered Horserace for 18 months or more, excluding periods of inactivity due to a Provisional Suspension or period of Ineligibility) by sending written notice thereof to the Authority and the Owner in accordance with the Agency's procedures. If the Owner disputes that retirement, while the dispute is pending the Covered Horse may not participate in any Timed and Reported Workout or Covered Horserace but must be made available for Testing. Upon resolution of the dispute, the Authority will notify the Agency whether the horse is retired and, therefore, no longer subject to Testing. If the Owner wishes to return the Covered Horse to participation in Timed and Reported Workouts or Covered Horseraces, the Owner must first provide the Agency with written notice and make the Covered Horse available for Testing for at least 4 months prior to such participation.

(6) The Agency may reduce the 4-month notice period in Rule 3050(b) to 2 months where the Owner of the Covered Horse submits an application establishing good cause to do so, and where the Agency approves such application based on a review conducted in accordance with the objectives of the Protocol.

(7) The Agency may forward notifications of retirement of Covered Horses to Interested Parties or other Persons with a need to know.

Rule 3060. Claiming Races and Voidable Claims

(a) Subject to Rule 3132(b), a claimed horse may be subject to Sample collection at a Claiming Race if requested (and paid for) by the claimant as part of the claiming procedure on the day of the Claim. If a Sample collected from the claimed horse results in an Anti-Doping Rule Violation or Controlled Medication Rule Violation, the Claim may be voided at the option of the claimant, and the claimant shall be entitled to the return from the seller of all sums paid for the claimed horse and of all reasonable expenses incurred after the date of the Claim. While awaiting test results, a claimant shall: (i) exercise due care in maintaining and boarding a claimed horse; and (ii) not materially alter a claimed horse.

(b) Any voided claim shall be recorded in Equibase.

Rule 3070. Amendment and Interpretation of the Protocol

(a) The Authority may amend the Protocol from time to time, as necessary to ensure that it remains fit for purpose, in accordance with section 3057(e) of the Act. Unless provided otherwise, any amendments will come into force on the date specified or (if no date is specified) on the date the amendment is approved by the Commission.

(b) Subject to Rule 3070(d), the Protocol shall be interpreted as an independent and autonomous text and not by reference to existing law or statutes.

(c) The Protocol has been adopted pursuant to the Act and shall be interpreted, where applicable, in a manner that is consistent with applicable provisions of the Act and the other rules in Rule 1000–9000 Series. In the event of any conflict between the Act and the Protocol, the Act shall prevail. In the event of any conflict between the Protocol and any other rules in Rule 1000–9000 Series, the Protocol shall prevail.

(d) The World Anti-Doping Code and related International Standards, procedures, documents, and practices (WADA Code Program), the comments annotating provisions of the WADA Code Program, and any case law interpreting or applying any provisions, comments, or other aspects of the WADA Code Program, may be considered when adjudicating cases relating to the Protocol, where appropriate.

Rule 3080. Transitional Provisions

(a) The Protocol shall not apply retroactively to matters pending before the Program Effective Date.

(b) A presence violation under Rule 3212 or Rule 3312 that occurs after the Program Effective Date as a result of Use or Administration prior to the Program Effective Date shall not constitute a violation of the Protocol.

(c) The relevant State Racing Commission retains authority (including results management) in relation to any anti-doping or controlled medication

matters taking place prior to the Program Effective Date.

(d) Changes to substances or methods covered by the Prohibited List or related Technical Document-Prohibited Substances shall not, unless they specifically provide otherwise, be applied retroactively. However, a Responsible Person or other Covered Person who is serving a period of Ineligibility on account of a Prohibited Substance or Prohibited Method that is later subject to a change in status (either because it is no longer prohibited or subject to lesser sanctions) may apply to the Agency for consideration of a reduction in the period of Ineligibility in light of that change in status. The Responsible Person may also apply to the Agency for consideration of a reduction in the period of Ineligibility applicable to his or her Covered Horse(s).

Rule 3090. Statute of Limitations

(a) No charge may be brought against a Covered Person or in relation to a Covered Horse in respect of an Anti-Doping Rule Violation unless the Covered Person or Responsible Person for the Covered Horse has been given notice, or notification has been reasonably attempted, within 10 years of the date the Anti-Doping Rule Violation is asserted to have occurred. Any violation of Rule 3229 is also subject to a 10-year limitation period.

(b) No charge may be brought against a Covered Person or in relation to a Covered Horse in respect of a Controlled Medication Rule Violation unless the Covered Person or Responsible Person for the Covered Horse has been given notice, or notification has been reasonably attempted, within 2 years of the date the Controlled Medication Rule Violation is asserted to have occurred. Any violation of Rule 3329 is also subject to a 2-year limitation period.

(c) Any violation of Rule 3510 is subject to a 4-year limitation period.

3110. The Prohibited List

Rule 3111. Prohibited Substances and Prohibited Methods

(a) The Prohibited List identifies Prohibited Substances and Prohibited Methods that are:

(1) prohibited at all times (Banned Substances and Banned Methods) on the basis of the Agency's determination that medical, veterinary, or other scientific evidence or experience supports their actual or potential (i) ability to enhance the performance of Covered Horses, (ii) masking properties, or (iii) detrimental impact on horse welfare; or

(2) prohibited for Use or Administration in relation to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample or Post-Work Sample, except as otherwise specified in the Prohibited List (Controlled Medication Substances and Controlled Medication Methods).

(b) Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (*e.g.,* anabolic steroids) or by specific reference to a particular substance or method.

(c) The Prohibited List is supplemented by the ''Technical Document—Prohibited Substances,'' which provides guidance on the Prohibited Substances that fall into the general categories listed in the Prohibited List and on Screening Limits, Thresholds, or Detection Times for those Prohibited Substances (as applicable), and also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and, therefore, are subject to more flexible sanctions.

(d) Certain Prohibited Substances may first be reported as Atypical Findings requiring further investigation before being declared as Adverse Analytical Findings, in accordance with the Atypical Findings Policy set out at Appendix 1 to the Protocol.

Rule 3112. Review and Publication of the Prohibited List and Related Technical Documents

The Agency will publish the Prohibited List on its website at least annually, following an opportunity for stakeholder comment. The Agency will review and consider such stakeholder comment and will provide recommended revisions to the Authority. Each new version of the Prohibited List will also be sent to the State Racing Commissions. The Authority (on recommendation of the ADMC, in consultation with the Agency) may revise the Prohibited List from time to time, subject to approval by the Commission. Revisions to the Prohibited List will go into effect on the date specified in the revised Prohibited List (which will not be any earlier than 90 days following its publication). The Agency will also publish any Technical Documents supplementing the Prohibited List (including the Technical Document-Prohibited Substances) on its website at least annually, following an opportunity for public comment. Any revisions to such Technical Documents will go into effect on the date specified in the revised Technical Document. All Covered Persons shall be bound by the Prohibited List and related Technical Documents (including the Technical Document-Prohibited Substances), 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 related Technical Documents (including the Technical Document-Prohibited Substances) and all revisions thereto.

Rule 3113. Validity of the Prohibited List and Related Technical Documents

The following decisions are final and shall not be subject to any challenge by any Covered Person or other Person on any basis, including any challenge based on an argument that the substance or method is not a masking agent or does not have the potential to enhance the performance of Covered Horses or have a detrimental impact on horse welfare:

(a) the Authority's determination of the Prohibited Substances and Prohibited Methods included on the Prohibited List or Technical Document-Prohibited Substances;

(b) the approval of the Prohibited List or Technical Document-Prohibited Substances by the Commission or the Authority;

(c) the classification of substances and methods into categories or classes on the Prohibited List or Technical Document-Prohibited Substances;

(d) the classification of a substance or method as a Banned Substance or Banned Method as opposed to a Controlled Medication Substance or Controlled Medication Method;

(e) the periods during which Prohibited Substances or Prohibited Methods are prohibited; and

(f) the classification of Prohibited Substances as either Specified Substances or non-Specified Substances.

Rule 3114. Monitoring Program

The Agency may approve a monitoring program regarding substances that are not on the Prohibited List or Technical Document-Prohibited Substances, if the Agency wishes to research or monitor such substances, including to identify potential patterns of misuse in horseracing. Laboratories will report the instances of reported Use or detected presence of monitored substances to the Agency, but the results of any such analyses shall not constitute an Anti-Doping Rule Violation or Controlled Medication Rule Violation. Nothing in this Rule 3114 or elsewhere in the Protocol prevents a Laboratory from sharing information with the Agency for any anti-doping or controlled

medication purpose or other purpose authorized by the Act. The list of substances in the monitoring program will be reviewed annually by the Agency.

3120. Proof of Violations

Rule 3121. Burden and Standard of Proof

(a) The Agency shall have the burden of establishing that a violation of the Protocol has occurred to the comfortable satisfaction of the hearing panel, bearing in mind the seriousness of the allegation that is made. This standard of proof in all cases is greater than a mere balance of probability (*i.e.,* a preponderance of the evidence) but less than clear and convincing evidence or proof beyond a reasonable doubt.

(b) Where the Protocol places the burden of proof on a Covered Person to rebut a presumption or to establish specified facts or circumstances, the standard of proof shall be by a balance of probability (*i.e.,* a preponderance of the evidence), except as provided in Rules 3122(c) and 3122(d).

Rule 3122. Methods of Establishing Facts and Presumptions

Facts related to violations may be established by any reliable means, including admissions. The following rules of proof shall apply:

(a) Analytical methods, Minimum Reporting Levels, Thresholds, Screening Limits, Decision Limits, and any other Laboratory reporting requirements approved by the Commission are presumed to be scientifically valid.

(b) Compliance with the Standards (as opposed to an alternative standard, practice, or procedure) will be sufficient to conclude that the procedures addressed by those Standards were performed properly.

(c) Laboratories are presumed to have conducted Sample analysis and custodial procedures in accordance with the Laboratory Standards. A Covered Person who is alleged to have committed a violation may rebut this presumption by establishing that a departure from the Laboratory Standards occurred that could reasonably have caused the Adverse Analytical Finding or other factual basis for any other violation asserted. Where the presumption is rebutted, the Agency shall have the burden of establishing that such departure did not cause the Adverse Analytical Finding or other factual basis for the violation asserted.

(d) Departures from any other Standards or any provisions of the Protocol shall not invalidate analytical results or other evidence of a violation, and shall not constitute a defense to a charge of such violation; provided, however, that if the Covered Person establishes that a departure from any other Standards or any provisions of the Protocol could reasonably have caused the Adverse Analytical Finding or other factual basis for the violation charged, the Agency shall have the burden to establish that such departure did not cause the Adverse Analytical Finding or other factual basis for the violation.

(e) Non-appealable and final factual findings of a court, arbitral tribunal, professional disciplinary body, 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 did not respect due process.

(f) A hearing panel may draw an inference adverse to a Covered Person who is asserted to have committed a violation of the Protocol based on the Covered Person's refusal to cooperate with the Agency, including any refusal to respond to questions put to him or her as part of an investigation or to appear at the hearing (either in person or remotely) and to answer questions put by the Agency or the hearing panel.

3130. Testing and Investigations

Rule 3131. Purpose of Testing and Investigations

Testing and investigations may be undertaken to assist in the effective policing and enforcement of the Protocol, including to obtain evidence regarding potential violations of the Protocol.

Rule 3132. Authority To Test

(a) Only the Agency (and those authorized by the Agency) may initiate and direct Testing on Covered Horses. The Agency has authority to conduct Testing both in and out of competition.

(b) No other entity (including State Racing Commissions, Racetracks, Race Organizers, and Training Facilities) may initiate or direct any Testing on Covered Horses. However, a State Racing Commission, Racetrack, Race Organizer, or other third party may request that the Agency initiate and direct enhanced or additional Testing (*e.g.,* in relation to a particular Covered Horserace). The Agency may accept or decline such request at its absolute discretion. Where the Agency accepts the request, the costs of Sample collection and analysis shall be borne by the entity requesting the additional or enhanced Testing. The Agency may conduct the Testing itself or delegate Testing (or aspects thereof) to the relevant State Racing Commission, subject to the applicable State Racing Commission electing to enter into an agreement with the Agency.

(c) Covered Horses may be subject to Testing at any time and any place where they are located by or on behalf of the Agency.

(d) A Covered Horse that is subject to a Provisional Suspension or period of Ineligibility, or that sustains a fatal condition, remains subject to Testing.

(e) In accordance with the Racetrack Safety Program, a Covered Horse may be required to submit to Sample collection (at the Owner's cost) following a Vets' List Workout in order to be released from the Veterinarians' List. Any Sample collected following a Vets' List Workout constitutes a Post-Race Sample, and, as a result, is subject to all of the same requirements that apply to Sample collection at Covered Horseraces. To schedule a Vets' List Workout, the Responsible Person or the Owner of the Covered Horse shall make a request to a Regulatory Veterinarian who shall, in turn, notify the Agency in order to make any necessary arrangements. The Agency must be given a minimum of 48 hours' notice of any Vets' List Workout.

Rule 3133. Requirements

(a) Testing. The Agency shall conduct test distribution planning and Testing in accordance with the Testing and Investigations Standards. The Agency may delegate authority to third parties, including State Racing Commissions (see Rule 3132), to conduct Testing (or aspects thereof) in accordance with the Testing and Investigations Standards under its supervision.

(b) Investigations and intelligence gathering. The Agency shall gather intelligence and conduct investigations, or delegate to third parties to do so under its supervision, in accordance with the Testing and Investigations Standards, which incorporate uniform rules and procedures in accordance with section 3054 of the Act providing for:

(1) access for the Agency to books, records, offices, racetrack facilities, and other places of business of Covered Persons that are used in the care, treatment, training, or racing of Covered Horses;

(2) the issuance and enforcement of subpoenas and subpoenas duces tecum by the Authority at the request of the Agency;

(3) the exercise of other investigatory powers similar in nature and scope to those exercised by State Racing

Commissions before the Program Effective Date; and

(4) the coordination and sharing of intelligence and information with the Authority, law enforcement (authorized by any government, including Federal, State, or international), State Racing Commissions, Racetracks, Race Organizers, Training Facilities, Laboratories, anti-doping organizations, equine regulatory bodies, or other relevant regulatory or disciplinary authorities.

Rule 3134. Sample Analysis

Samples shall be analyzed in accordance with the principles set forth in Rules 3135 through 3139.

Rule 3135. Ownership of Samples

Samples collected under the Protocol are the property of the Authority, and the Authority is entitled (subject to Rule 3138(b)) to determine all matters regarding access to and the analysis and disposal of such Samples.

Rule 3136. Use of Approved Laboratories and Other Laboratories

(a) The Agency will publish a list of approved Laboratories, which may be revised from time to time.

(b) Subject to paragraph (d) below, Samples collected by or on behalf of the Agency pursuant to the Protocol will be analyzed by approved Laboratories. Only approved Laboratories may declare an Adverse Analytical Finding.

(c) Selection of Laboratories.

(1) Subject to paragraph (2) below, a State Racing Commission may select a Laboratory to analyze A Samples or TCO2 Samples collected in its State. If a State Racing Commission does not select a Laboratory, the selection of the Laboratory to analyze such Samples shall be determined exclusively by the Agency.

(2) The Agency shall have the authority to require specific Samples to be directed to and analyzed by Laboratories having special expertise in the required analysis.

(3) The selection of the Laboratory for any B Sample analysis shall be determined exclusively by the Agency. The B Sample analysis (if applicable) will be performed in a different Laboratory from the A Sample analysis, except if provided otherwise in the Laboratory Standards.

(d) In accordance with Rule 3122, facts related to violations of the Protocol may be established by any reliable means. This would include, for example, laboratory analysis or other forensic testing conducted reliably outside of Agency-approved laboratories.

Rule 3137. Purpose of Sample Analysis

(a) General. Samples, related analytical data, Doping Control information, and Medication Control information shall be analyzed (1) to detect the presence of Prohibited Substances and Prohibited Methods identified on the Prohibited List (or Technical Document—Prohibited Substances) and other substances as may be directed pursuant to Rule 3114, (2) 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 (3) for any other legitimate purpose.

(b) Research on Samples and Data. Samples, related analytical data, Doping Control information, and Medication Control information may be used for anti-doping or medication control research purposes. However, the results of any analyses performed for such research purposes may not be used as the basis for pursuing an Anti-Doping Rule Violation or Controlled Medication Rule Violation.

Rule 3138. Standards for Sample Analysis and Reporting

(a) General. Laboratories may not accept or analyze any Samples from Covered Horses that were not collected by or on behalf of the Agency or otherwise authorized by the Agency. Laboratories shall analyze Samples and report results in accordance with the Laboratory Standards. The results of all Sample analyses must be sent exclusively to the Agency via secure transmission in a form designated by the Agency. All communications must be conducted in such a way that the results of the Sample analyses are kept confidential.

(b) Further Analysis of a Sample prior to or during Results Management. Further Analyses may be conducted, without limitation, on a Sample prior to the time that it is reported as negative or prior to the time that the Agency notifies a Covered Person that the Sample is the basis for an Anti-Doping Rule Violation or Controlled Medication Rule Violation. If the Agency notifies a Covered Person that the Sample is the basis for an Anti-Doping Rule Violation or Controlled Medication Rule Violation, and the Agency wishes to conduct Further Analyses on that Sample after such notification, it may do so only with the consent of the Covered Person or the approval of the hearing panel adjudicating the case against the Covered Person.

(c) Further Analysis of a Sample after it has been reported as negative or has otherwise not resulted in an Anti-Doping Rule Violation or Controlled Medication Rule Violation. A Sample that has been reported as negative or has otherwise not resulted in a charge may be stored and subjected to Further Analyses for the purpose described in Rule 3137 at any time exclusively at the direction of the Agency. Any Sample storage and Further Analysis initiated by the Agency shall be at the Agency's expense. Further Analysis of Samples shall be conducted in accordance with the Laboratory Standards.

(d) Split of A or B Sample. Where, in exceptional circumstances, the Laboratory (on instruction from the Agency) is required to further split an A or B Sample for the purpose of using the first part of the resulting split Sample for an A Sample analysis and the second part of the resulting split Sample for B confirmation, the procedures and analysis shall be conducted in accordance with the Laboratory Standards.

Rule 3139. The Agency's Right To Take Possession of Samples and Related Data

The Agency may at any time, with or without prior notice, take physical possession of any Sample collected by or on behalf of the Agency and any related analytical data or information in the possession of a Laboratory. Upon request by the Agency, the Laboratory in possession of the Sample or related data shall grant access to and enable the Agency to take physical possession of the Sample or data as soon as possible.

Rule 3140. Clearance Testing

Clearance testing for a Covered Horse at the request of a Covered Person (*i.e.,* testing to determine if Controlled Medications Substances have cleared the horse's system) may be performed by a Laboratory only if in advance of such testing (1) the Agency approves such request (which approval may be subject to conditions determined by the Agency), and (2) the Covered Person pays for all of the costs of Sample collection and analysis. The Agency may pursue any violation of the Protocol that is evidenced by the results of the clearance testing.

3210. Anti-Doping Rule Violations

Rule 3211. Definition of Anti-Doping Rule Violation and Responsibility for Violations

(a) Doping cases will be initiated based on the assertion that one or more of Rules 3212 through 3216 has been violated (each, an Anti-Doping Rule Violation).

(b) The Anti-Doping Rule Violations described below may only be committed

by Covered Persons, but the Consequences for Anti-Doping Rule Violations may apply to both the Covered Person(s) who commit(s) the violation and any Covered Horse(s) implicated by the violation.

(c) All Covered Persons are responsible for knowing what constitutes an Anti-Doping Rule Violation and what Banned Substances and what Banned Methods are included on the Prohibited List and Technical Document–Prohibited Substances.

Rule 3212. Presence of a Banned Substance

(a) It is the personal and non-delegable duty of the Responsible Person to ensure that no Banned Substance is present in the body of his or her Covered Horse(s). The Responsible Person is therefore strictly liable for any Banned Substance or its Metabolites or Markers found to be present in a Sample collected from his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3212 Anti-Doping Rule Violation.

(b) Sufficient proof of a Rule 3212 Anti-Doping Rule Violation is established by any of the following:

(1) the presence of a Banned Substance or its Metabolites or Markers in the Covered Horse's A Sample where the Responsible Person waives analysis of the B Sample and the B Sample is not analyzed;

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

(3) where, in exceptional circumstances, the Laboratory (on instruction from the Agency) further splits the A or B Sample into two parts in accordance with the Laboratory Standards, the analysis of the second part of the resulting split Sample confirms the presence of the same Banned Substance or its Metabolites or Markers as were found in the first part of the split Sample, or the Responsible Person waives analysis of the second part of the split Sample.

(c) The general rule is that the presence of any amount of a Banned Substance or its Metabolites or Markers in a Sample collected from a Covered Horse constitutes an Anti-Doping Rule Violation by the Responsible Person of that Covered Horse.

(d) As an exception to the general rule of Rule 3212(c), the Prohibited List, Standards, or Technical Documents may establish special criteria for the reporting or the evaluation of certain Banned Substances, including a Minimum Reporting Level, Screening Limit, Threshold, or Decision Limit.

Rule 3213. Use or Attempted Use of a Banned Substance or a Banned Method

(a) Subject to Rule 3213(c), the Use or Attempted Use of a Banned Substance or Banned Method in relation to a Covered Horse constitutes an Anti-Doping Rule Violation. The success or failure of that Use or Attempted Use is not material. For a Rule 3213 violation to be committed, it is sufficient that the Banned Substance or Banned Method was Used or Attempted to be Used.

(b) It is the personal and non-delegable duty of the Responsible Person to ensure that no Banned Substance or Banned Method is Used in relation to his or her Covered Horse. The Responsible Person is therefore strictly liable for any Use of a Banned Substance or Banned Method in relation to his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3213 Anti-Doping Rule Violation of Use. However, in accordance with the definition of Attempt, it is necessary to show intent on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3213 Anti-Doping Rule Violation of Attempted Use.

(c) The presence of a Prohibited Substance or of evidence of Use of a Prohibited Method in the Covered Horse's Sample or other evidence of Use of such Prohibited Substance or Prohibited Method shall not be considered an Anti-Doping Rule Violation if it is determined to have resulted from Use of the Banned Substance or Banned Method prior to the horse becoming a Covered Horse. However, any such Use is subject to Rule 3040(b)(9) and may be reported to the relevant State Racing Commission.

Rule 3214. Other Anti-Doping Rule Violations Involving Banned Substances or Banned Methods

The following acts and omissions constitute Anti-Doping Rule Violations by the Covered Person(s) in question:

(a) Possession of a Banned Substance or a Banned Method, unless there is compelling justification for such Possession.

(b) Trafficking or Attempted Trafficking in any Banned Substance or Banned Method.

(c) Administration or Attempted Administration to a Covered Horse of any Banned Substance or any Banned Method.

Rule 3215. Evading Collection of a Sample From a Covered Horse; Refusing or Failing Without Compelling Justification To Submit a Covered Horse To Sample Collection; or Refusing or Failing To Comply With All Sample Collection Procedure Requirements

(a) Except as provided in Rule 3215(d), each of the following constitutes an Anti-Doping Rule Violation: (1) evading collection of a Sample from a Covered Horse, (2) refusing or failing without compelling justification to submit a Covered Horse to Sample collection after notification by a duly authorized person, or (3) refusing or failing to comply with all Sample collection procedure requirements.

(b) Responsible Persons are responsible for ensuring compliance with Rules 3040(b)(1) and 3040(b)(2). A Responsible Person may delegate the submission and supervision of the Covered Horse to a third party, but the Responsible Person remains responsible for the Covered Horse throughout the Sample collection process and for the acts and omissions of his or her delegate. Therefore, the Responsible Person shall be deemed liable for any evasion by his or her delegate of Sample collection, any refusal or failure by his or her delegate without compelling justification to submit the Covered Horse to Sample collection, or any refusal or failure by his or her delegate to comply with all Sample collection procedure requirements.

(c) Sample collection shall ordinarily be conducted where the Covered Horse is located (*e.g.,* Racetrack, Training Facility, or private facility), unless the Agency agrees that the Covered Horse may be transported to another agreed location (*e.g.,* a nearby Racetrack).

(d) No violation occurs where a Covered Horse is made available for Sample collection, but a Sample is not collected because the Covered Horse is intractable.

Rule 3216. Other Anti-Doping Rule Violations

The following acts and omissions constitute Anti-Doping Rule Violations by the Covered Person(s) in question:

(a) Tampering or Attempted Tampering by a Covered Person with any part of Doping Control or Medication Control;

(b) a Covered Person assisting, encouraging, aiding, abetting, conspiring, covering up, or engaging in

any other type of intentional complicity or Attempted complicity involving (1) an Anti-Doping Rule Violation or Attempted Anti-Doping Rule Violation, or (2) a violation of Rule 3229 by another Covered Person.

(c) Prohibited Association:

(1) Association by a Covered Person in a professional or sport-related capacity with any Person who:

(i) is serving a period of Ineligibility imposed pursuant to the Protocol or is serving a period of ineligibility imposed pursuant to anti-doping rules administered by any other equine regulatory body or anti-doping organization; or

(ii) has been found in a criminal, disciplinary, or professional proceeding to have engaged in conduct that would have constituted a violation of the Protocol if it had been applicable to such Person at the relevant time. The disqualifying status of such Person shall last for the longer of:

(A) 6 years from the criminal, professional, or disciplinary decision; and (B) the duration of the criminal, disciplinary, or professional sanction imposed; or

(iii) is serving as a front or intermediary for an individual falling within paragraph (i) or (ii) above.

(2) To establish a violation of Rule 3216(c), the Agency must establish that the Covered Person knew at the relevant time of the Person's disqualifying status. It is presumed that any association with the Person described in Rules 3216(c)(1)(i) and (ii) is in a professional or sport-related capacity, and the burden shall be on the Covered Person to rebut that presumption.

(3) It shall be a defense to a charge of violation of Rule 3216 if the Covered Person establishes that the association with the Person could not have been reasonably avoided.

(d) Acts by a Covered Person to discourage or retaliate against reporting to authorities.

(1) Where such conduct does not otherwise constitute a violation under Rule 3216(a) (Tampering or Attempted Tampering), each of the following constitutes an Anti-Doping Rule Violation under this Rule 3216(d):

(i) any act that threatens or seeks to intimidate another Person with the intent of discouraging that Person from the good faith reporting of information that relates to an alleged Anti-Doping Rule Violation or other alleged non-compliance with the Protocol to the Agency or other appropriate Person; and

(ii) retaliation against a Person who, in good faith, has provided evidence or information that relates to an alleged Anti-Doping Rule Violation or other alleged non-compliance with the Protocol to the Agency or other appropriate entity or Person.

(2) For purposes of Rule 3216(d), threatening or seeking to intimidate a Person, and retaliation against a Person, include an act taken against such Person that lacks a good faith basis or is a disproportionate response.

3220. Sanctions

Rule 3221. Disqualification of the Covered Horse's Results

(a) Automatic Disqualification of results.

(1) An Anti-Doping Rule Violation that arises from a Post-Race Sample, or that occurs during the Race Period, automatically leads to Disqualification of the results of the Covered Horse obtained on the Race Day(s) that fall(s) within the Race Period, even if any other sanction for the violation is eliminated or reduced under Rules 3224, 3325, or 3226.

(2) In circumstances where an EAD Notice has been sent as required under Rule 3245, and the B Sample analysis confirms the A Sample analysis, or the right to request the analysis of the B Sample is waived, the Agency, the Responsible Person, and the Owner of the Covered Horse in question may agree to apply Rule 3221 immediately, *i.e.,* prior to adjudication of any other issue, or (in the absence of such agreement) any one of them may request that the Arbitral Body apply Rule 3221 immediately.

(b) Disqualification of subsequent results.

(1) Subject to paragraph (2), in addition to the automatic Disqualification of results under Rule 3221(a), any other results that the Covered Horse obtained from the date the Anti-Doping Rule Violation first occurred, as well as during any period of retroactive Ineligibility, shall be Disqualified, unless it is established by the Responsible Person that fairness requires otherwise.

(2) If the Anti-Doping Rule Violation occurs in relation to a Claiming Race in which the Covered Horse is claimed, Rule 3221(b)(1) shall not apply to any results obtained by the Covered Horse under the new ownership.

(c) Consequence of Disqualification of results:

(1) If a Covered Horse has results Disqualified under the Protocol, all purses and other compensation, prizes, trophies, points, and rankings are forfeited and must be repaid or surrendered (as applicable) to the Race Organizer, and the results of the other Covered Horses in the race(s) in question must be adjusted accordingly and the purses, prizes, and trophies redistributed. Purses, prizes, trophies, and other compensation shall (where possible) be withheld for the Covered Horse in issue pending resolution of the relevant charge.

(2) The Covered Horses that participated in a Covered Horserace involving an alleged Anti-Doping Rule Violation are often entered in other Covered Horseraces prior to the final adjudication of the violation. The ultimate Disqualification of a Covered Horse in connection with final adjudication of a violation shall only impact that horse's conditions for eligibility. By way of example, a maiden that is Disqualified after finishing first in a maiden race shall remain a maiden until it has won another race, but the runner-up in the disputed Covered Horserace shall not be considered the winner for purposes of its future condition eligibility. The adjustment to the Disqualified horse's condition eligibility shall only occur once the violation has been finally adjudicated.

Rule 3222. Ineligibility for Covered Horses

(a) For a violation of Rule 3212 (presence), 3213 (Use or Attempted Use), or Rule 3214(c) (Administration or Attempted Administration), the Covered Horse involved shall be Ineligible for the period designated in the Prohibited List for the Banned Substance or Banned Method in issue.

(b) For a violation of Rule 3215 involving evasion of Sample collection, the Covered Horse shall be Ineligible for 18 months. For a violation of Rule 3215 involving refusal or failure to submit to Sample collection, or refusal or failure to comply with all Sample collection procedure requirements, the Covered Horse shall be Ineligible for 18 months, unless it is established by the Responsible Person that fairness requires otherwise, in which case the period of Ineligibility may be reduced, depending on the specific circumstances of the case and considerations of horse welfare.

(c) Rule 3228 on increased periods of Ineligibility for repeat offenders does not apply to Covered Horses.

(d) The period of Ineligibility for a Covered Horse shall be deemed to commence on the date that the violation occurred (which, in the case of a Rule 3212 violation, shall be the date that the positive Sample was collected, even if the Covered Horse has participated in Timed and Reported Workouts or Covered Races after that date).

Rule 3223. Ineligibility and Financial Penalties for Covered Persons

(a) General.

(1) The periods of Ineligibility and financial penalties set out in this Rule 3223 apply to the Covered Person's first doping offense. Where an offense is not the Covered Person's first doping offense, Rule 3228 applies.

(2) Unless specified otherwise, the periods of Ineligibility set out in this Rule 3223 are subject to potential elimination, reduction, or suspension pursuant to Rules 3224 to 3226 or potential increase pursuant to Rule 3227.

(3) In accordance with Rule 3247(i), any period of Provisional Suspension served by the Covered Person shall be credited against the period of Ineligibility ultimately imposed on that Covered Person for the violation in question.

(b) Consequences.

Subject to Rule 3223(a), and in addition to any other Consequences that apply under the Protocol (including Disqualification), the periods of Ineligibility and financial penalties specified below shall apply to a Covered Person for his or her first Anti-Doping Rule Violation:

Anti-doping rule violation (first offense in ten (10) year period)	Period of ineligibility	Financial penalties
Presence (Rule 3212); Use or Attempted Use (Rule 3213); Possession (Rule 3214(a)); or Administration or Attempted Administration (Rule 3214(c)).	2 years	Fine of up to $25,000 or 25% of the total purse (whichever is greater); and Payment of some or all of the adjudication costs and the Agency's legal costs.
Trafficking or Attempted Trafficking (Rule 3214(b)).	Minimum of 4 years up to lifetime Ineligibility, depending on the seriousness of the violation. A violation involving a Minor shall be considered a particularly serious violation and shall result in lifetime Ineligibility for the Covered Person who commits it. A violation that may also violate non-sporting laws and regulations shall be reported to the competent administrative, professional, or judicial authorities.	Fine of up to $50,000 or 50% of the total purse (whichever is greater); and Payment of some or all of the adjudication costs and the Agency's legal costs.
Evading collection of a Sample from a Covered Horse; refusing or failing without compelling justification to submit a Covered Horse to Sample collection; or refusing or failing to comply with all Sample collection procedure requirements (Rule 3215); or Tampering or Attempted Tampering (Rule 3216(a)).	4 years, except: in the case of failing to submit to Sample collection, if the Covered Person can establish that the failure was not intentional, the period of Ineligibility shall be in a range between 3 months to 2 years, depending on his or her degree of Fault; and. in all other cases, if the Covered Person can establish exceptional circumstances that justify a reduction of the period of Ineligibility, the period of Ineligibility shall be in a range from 3 months to 4 years, depending on his or her degree of Fault.	Fine up to $50,000 or 50% of the total purse (whichever is greater); and Payment of some or all of the adjudication costs and the Agency's legal costs.
Complicity or Attempted complicity (Rule 3216(b)).	Same Consequences that apply to the principal actor, absent mitigating or aggravating circumstances.	
Prohibited Association (Rule 3216(c))	2 years, subject to a reduction down to a minimum of 1 year, depending on the Covered Person's degree of Fault and other circumstances of the case.	Fine up to $25,000 or 25% of the total purse (whichever is greater); and Payment of some or all of the adjudication costs and the Agency's legal costs.
Acts to discourage or retaliate against reporting (Rule 3216(d)).	2 years up to lifetime Ineligibility, depending on the seriousness of the violation.	Fine of up to $50,000 or 50% of the total purse (whichever is greater); andLI≤Payment of some or all of the adjudication costs and the Agency's legal costs.

(c) Commencement of the period of Ineligibility for a Covered Person.

(1) Except as otherwise provided in this Rule 3223, the period of Ineligibility imposed on any Covered Person shall start on the date the period of Ineligibility is accepted or otherwise imposed in accordance with the Protocol.

(2) Where a Covered Person is already serving a period of Ineligibility for another violation of the Protocol, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends.

(3) 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 Results Management, and the Covered Person can establish that such delays are not attributable to him or her, the start date of the period of Ineligibility may be deemed back-dated to reflect such delays, but in no event may it be deemed back-dated to a date before the Anti-Doping Rule Violation last occurred. All competitive results achieved during the period of Ineligibility by the Covered Person or Covered Horse in issue, including retroactive Ineligibility, shall be Disqualified, unless it is established by the Covered Person that fairness requires otherwise.

Rule 3224. Elimination of the Period of Ineligibility Where There Is No Fault or Negligence

(a) If a Covered Person establishes in an individual case that he or she bears No Fault or Negligence for the Anti-Doping Rule Violation(s) charged, the otherwise applicable period of

Ineligibility and other Consequences for such Covered Person shall be eliminated (except for those set out in Rule 3221(a) and Rule 3620). When the violation is of Rule 3212 (presence of a Banned Substance), the Covered Person must also establish how the Banned Substance entered the Covered Horse's system as a pre-condition to application of this Rule 3224(a). In the event the period of Ineligibility otherwise applicable is eliminated pursuant to this Rule 3224, the Anti-Doping Rule Violation shall not be considered a prior violation for the purpose of Rule 3228.

(b) Rule 3224 only applies in exceptional circumstances. In particular, it will not apply where the Banned Substance found to be present in a Sample: (1) came from a mislabeled or contaminated supplement; or (2) was administered to the Covered Horse by veterinary or other support personnel without the knowledge of the Responsible Person.

(c) A finding that the Covered Person bears No Fault or Negligence for an Anti-Doping Rule Violation shall not affect the Consequences of that violation that apply to the Covered Horse (*i.e.,* Ineligibility in accordance with Rule 3222(a) and Disqualification of results in accordance with Rule 3221).

Rule 3225. Reduction of the Period of Ineligibility Where There Is No Significant Fault or Negligence

Reductions under this Rule 3225 are mutually exclusive and not cumulative, *i.e.,* no more than one of them may be applied in a particular case.

(a) General rule.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question, then (unless Rule 3225(b) or 3225(c) applies) the period of Ineligibility shall be fixed between 3 months and 2 years, depending on the Covered Person's degree of Fault.

(b) Specified Substances.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question, and the violation involves only a Specified Substance, the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, 2 years of Ineligibility, depending on the Covered Person's degree of Fault.

(c) Contaminated Products or other contamination.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Anti-Doping Rule Violation in question and that the Banned Substance in question came from a Contaminated Product or from another form of contamination, the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, 2 years of Ineligibility, depending on the Covered Person's degree of Fault.

Rule 3226. Elimination, Reduction, or Suspension of Period of Ineligibility or Other Consequences for Reasons Unrelated to Degree of Fault

(a) Substantial Assistance. The Agency may suspend all or part of the Consequences imposed on a Covered Person in an individual doping case—other than Disqualification of results pursuant to Rule 3221—based on the following:

(1) The Covered Person provides Substantial Assistance to the Agency, the Authority, or a State Racing Commission, a criminal authority, or a professional disciplinary body that results in:

(i) the Agency discovering or bringing forward an Anti-Doping Rule Violation or a Controlled Medication Rule Violation by another Covered Person; or

(ii) 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 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 also made available to the Agency.

(2) The extent to which the otherwise applicable period of Ineligibility may be suspended shall be based on the seriousness of the Anti-Doping Rule Violation committed by the Covered Person and the degree to which the Substantial Assistance provided by the Covered Person assists the effort to promote doping-free racing, compliance with the Protocol, or the integrity of racing. In any event, no more than three-quarters of the otherwise applicable period of Ineligibility may be suspended. If the otherwise applicable period of Ineligibility is a lifetime, the non-suspended period under this section must be no less than 8 years. For purposes of this Rule 3226, the otherwise applicable period of Ineligibility shall not include any period of Ineligibility that could be added under Rule 3228(c)(2).

(3) If so requested, the Agency shall allow the Covered Person who seeks to provide Substantial Assistance to provide the information to the Agency subject to a Without Prejudice Agreement.

(4) If the Covered Person fails to continue to cooperate or fails to provide the complete, accurate, and credible Substantial Assistance promised, the Agency shall reinstate the original Consequences. That decision is not subject to review.

(b) Voluntary Admission of an Anti-Doping Rule Violation in the absence of other evidence. If (1) the Covered Person voluntarily admits the commission of an Anti-Doping Rule Violation before receiving the EAD Notice or (in the case of a Rule 3212 violation) before having received notice of a Sample collection that could establish the Anti-Doping Rule Violation, and (2) that admission is the only reliable evidence of the violation at the time the admission is made, the otherwise applicable period of Ineligibility may be reduced by up to one-half.

(c) Application of multiple grounds for reduction of a sanction. If the Covered Person establishes entitlement to a reduction or suspension of the period of Ineligibility under 2 or more of Rules 3224, 3225, or 3226, the otherwise applicable period of Ineligibility shall be determined in accordance with Rules 3223, 3224, and 3225 before applying any reduction or suspension under Rule 3226. If the Covered Person establishes entitlement to a reduction or suspension of the period of Ineligibility under Rule 3226, up to three-quarters of the otherwise applicable period of Ineligibility may be reduced or suspended.

(d) Reductions for certain Anti-Doping Rule Violations based on early admission and acceptance of sanction.

(1) If the Agency notifies a Covered Person of a potential Anti-Doping Rule Violation that carries an asserted period of Ineligibility of 4 or more years (including any period of Ineligibility asserted under Rule 3227), if the Covered Person admits the violation and accepts the asserted period of Ineligibility no more than 7 days after receiving the Charge Letter, the period of Ineligibility to be served will be automatically reduced by 1 year (but no further reduction shall be allowed under any other Rule).

(2) If the Agency notifies a Covered Person of a potential Anti-Doping Rule Violation that carries an asserted period of Ineligibility of 2 years or more years, but less than 4 years (including any period of Ineligibility asserted under Rule 3227), if the Covered Person admits the violation and accepts the asserted period of Ineligibility no more than 7 days after receiving the Charge Letter, the period of Ineligibility to be served will be automatically reduced by 6 months (but no further reduction shall be allowed under any other Rule).

Rule 3227. Aggravating Circumstances

(a) In an individual case involving an Anti-Doping Rule Violation that is not a Rule 3214(b) violation (Trafficking or Attempted Trafficking) or a Rule 3216(d) violation (acts to discourage or retaliate against reporting), if the Agency establishes that Aggravating Circumstances are present, the period of Ineligibility otherwise applicable shall be increased by up to 2 years, depending on the seriousness of the Aggravating Circumstances, unless the Covered Person establishes that he or she did not knowingly commit the Anti-Doping Rule Violation. Where the period of Ineligibility is increased pursuant to this Rule, an additional fine of up to $10,000 or an additional 10% of the total purse (whichever is greater) may also be imposed.

(b) Actions and circumstances constituting Aggravating Circumstances include:

(1) Administration of a Banned Substance or Use of a Banned Method that is detrimental to the health and welfare of the horse or is designed to deceive the betting public;

(2) the presence in the Covered Horse's Sample of a combination of Banned Substance(s) and Controlled Medication Substance(s);

(3) prior violations under the Protocol; or

(4) the Covered Person engaged in deceptive or obstructive conduct to avoid the detection or adjudication of an Anti-Doping Rule Violation or a Controlled Medication Rule Violation, for which the Covered Person has not been separately sanctioned for Tampering.

(c) For the avoidance of doubt, the examples set out in Rule 3227(b) are not exhaustive and other similar circumstances or conduct may also be deemed to amount to Aggravating Circumstances that justify the imposition of a longer period of Ineligibility.

Rule 3228. Increased Sanctions for Repeat Offenders

(a) For purposes of this Rule 3228, the following prior Anti-Doping Rule Violations shall be disregarded: (1) violations that occurred more than 10 years prior to the violation now being sanctioned; and (2) violations for which the Covered Person was found to bear No Fault or Negligence.

(b) Subject to Rule 3228(a), and in addition to any other Consequences that apply under the Protocol (including Disqualification), the periods of Ineligibility and financial penalties specified below shall apply to any Covered Person who commits a second or subsequent Anti-Doping Rule Violation:

Number of anti-doping rule violations (in 10-year period)	Period of ineligibility	Financial penalties
Second Anti-Doping Rule Violation	The period of Ineligibility shall be the greater of: (a) a 6-month period of Ineligibility; or (b) a period of Ineligibility in the following range, taking into account the entirety of the circumstances and the Covered Person's degree of Fault with respect to the second violation: (i) the sum of the period of Ineligibility imposed for the first Anti-Doping Rule Violation, plus the period of Ineligibility otherwise applicable to the second Anti-Doping Rule Violation treated as if it were a first violation; and (ii) twice the period of Ineligibility otherwise applicable to the second Anti-Doping Rule Violation treated as if it were a first violation.	Fine of up to $50,000 or 50% of the total purse (whichever is greater); and Payment of some or all of the adjudication costs and the Agency's legal costs.
Third (or subsequent) Anti-Doping Rule Violation.	Lifetime Ineligibility, except if the third violation satisfies the conditions for elimination or reduction of the period of Ineligibility under Rule 3224 or Rule 3225, in which case the period of Ineligibility shall be from 8 years to lifetime Ineligibility. If the above exception applies, the same rule shall apply to any subsequent violation.	Fine of up to $100,000 or 100% of the total purse (whichever is greater); and Payment of some or all of the adjudication costs and the Agency's legal costs.

(c) Additional rules for certain multiple violations.

(1) Multiple violations for the same Banned Substance/Method incurred by a Covered Person in relation to the same Covered Horse prior to delivery of an EAD Notice may (at the Agency's discretion) be treated together as a single Anti-Doping Rule Violation, unless the facts demonstrate that there was more than one administration. Multiple violations for the same Banned Substance/Method incurred by a Covered Person in relation to different Covered Horses prior to delivery of an EAD Notice may (at the Agency's discretion) each be treated as a first Anti-Doping Rule Violation. Where multiple Banned Substances are detected in a single Post-Race Sample or Post-Work Sample, each Banned Substance may (at the Agency's discretion) be treated as a separate violation.

(2) If the Agency establishes that, prior to receiving an EAD Notice in respect of one Anti-Doping Rule Violation, the Covered Person committed an additional Anti-Doping Rule Violation that occurred 12 months or more before or after the violation asserted in that EAD Notice, the period of Ineligibility for the additional violation shall be calculated as if the additional violation were a stand-alone first violation, and that period of Ineligibility will run consecutively to (rather than concurrently with) the period of Ineligibility imposed for the first-notified violation. Where this Rule applies, the violations taken together will constitute a single violation for purposes of Rule 3228.

(3) If a Doping Control process results in the assertion of an Anti-Doping Rule

Violation, and the Agency establishes that the Covered Person committed an independent violation of Rule 3216(a) (Tampering) in connection with that Doping Control process, the Rule 3216(a) (Tampering) violation shall be treated as a stand-alone violation and the period of Ineligibility for such violation shall be served consecutively to, rather than concurrently with, the period of Ineligibility imposed for the other Anti-Doping Rule Violation. Where this Rule 3228(c)(3) is applied, the violations taken together shall constitute a single violation for purposes of Rule 3228.

(4) If the Agency establishes that the Covered Person has committed a further violation of the Protocol during a period of Ineligibility, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends.

(d) Violations involving both a Banned Substance or Method and a Controlled Medication Substance or Method.

Where a Covered Person is found, based on a common set of facts, to have committed a (1) violation involving one or more Banned Substance(s) or Banned Method(s), and (2) a violation involving one or more Controlled Medication Substance(s) or Controlled Medication Method(s), they shall be treated as separate violations, but shall be adjudicated together in consolidated proceedings pursuant to the procedure that applies to Anti-Doping Rule Violations under the Arbitration Procedures.

Rule 3229. Status During Provisional Suspension or Ineligibility

(a) While serving a Provisional Suspension or period of Ineligibility for an Anti-Doping Rule Violation:

(1) a Covered Horse may not participate in any Timed and Reported Workout or Covered Horserace, but shall remain subject to Testing;

(2) a Covered Person may not participate in any capacity in any activity involving Covered Horses, or in any other activity (other than authorized anti-doping education or rehabilitation programs) taking place at a Racetrack or Training Facility; nor shall he or she permit anyone to participate in any capacity on his or her behalf in any such activities, except to the extent that the Covered Person is an Owner and the activity is necessary to ensure the safekeeping and wellbeing of the horse during the period of such Owner's Provisional Suspension or Ineligibility.

(b) The Covered Horse(s) of an Owner or Trainer who is subject to a Provisional Suspension or period of Ineligibility shall be subject to the following restrictions:

(1) The Covered Horse(s) of a Trainer who is subject to a Provisional Suspension or period of Ineligibility may not participate in any Timed and Reported Workout or Covered Horserace unless and until they have been transferred to another Covered Person. For the ''transfer'' to be valid, (i) the transfer must be registered with the Authority in accordance with its procedures, and (ii) the Covered Horses must also be physically relocated to facilities under the care or control of a Covered Person who is not affiliated with the suspended Trainer (and failure to comply may constitute an Anti-Doping Rule Violation under Rule 3216(c), *i.e.,* Prohibited Association).

(2) The Covered Horse(s) of an Owner who is subject to a Provisional Suspension or period of Ineligibility may not participate in any Timed and Reported Workout or Covered Horserace unless and until they have been transferred in a bona fide transaction to a different Owner. If an Immediate Family Member has any ownership or property interest in the Covered Horse(s) following such transfer, the transfer shall not constitute a bona fide transaction to a different Owner.

Rule 3230. Consequences for Violation of the Prohibition on Participation During Ineligibility or Provisional Suspension Under Rule 3229

(a) Consequences for violation of the prohibition on participation during Ineligibility.

(1) If a Covered Person violates the prohibition against participation during Ineligibility described in Rule 3229, any results obtained from 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 Covered Person's original period of Ineligibility.

(2) If a Covered Horse participates in any Timed and Reported Workout or Covered Horserace in violation of the prohibition against participation during Ineligibility described in Rule 3229, any results obtained from such participation shall be Disqualified and the Responsible Person for that Covered Horse shall receive the following period of Ineligibility:

(i) if the Responsible Person was subject to an original period of Ineligibility, 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. If the original period of Ineligibility has already expired, the new period of Ineligibility shall start on the date that it is accepted or imposed; or

(ii) if the Responsible Person was not subject to an original period of Ineligibility, the period of Ineligibility for violating Rule 3229 shall be from a reprimand to 1 year, depending on the Covered Person's degree of Fault.

(b) Consequences for violation of the prohibition on participation during Provisional Suspension.

(1) A Covered Person who violates the prohibition against participation during a Provisional Suspension shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

(2) If a Covered Horse participates in any Timed and Reported Workout or Covered Horserace in violation of the prohibition against participation during a Provisional Suspension described in Rule 3229, the Responsible Person for that Covered Horse and the Covered Horse shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

(c) The consequence of Disqualification under this Rule 3230 shall be the same as set out in Rule 3221(c).

(d) The Arbitral Body (or the Agency, if the Covered Person admits the violation and accepts the consequences) shall determine whether there has been a violation of the prohibition against participation during Provisional Suspension or Ineligibility and apply the appropriate consequences pursuant to Rule 3261.

Rule 3231. Automatic Public Disclosure

A mandatory part of each sanction shall include automatic Public Disclosure in accordance with Rule 3620.

Rule 3232. Conditions Precedent to Reinstatement for Covered Persons

(a) To be reinstated after commission of an Anti-Doping Rule Violation, the Covered Person must have respected his or her period of Ineligibility (Rule 3229); and repaid or surrendered any purses and other compensation, prizes, trophies, points, and rankings forfeited pursuant to Rule 3221, and paid any fines and reimbursed any costs imposed or accepted to the Agency, unless an installment plan was established pursuant to Rule 3232(b), in which case the Covered Person must have made all payments due under that plan. If any installment(s) subsequently become(s) overdue under that plan (*i.e.,* after reinstatement), the Covered Person and the Covered Horses under his or her ownership or training may not

participate in any Timed and Reported Workout or Covered Horserace until such overdue installment(s) is/are paid in full.

(b) Where fairness requires, the Agency or the Arbitral Body may establish an installment plan for repayment of amounts due to be paid or reimbursed under the Protocol. The payment schedule may extend beyond any period of Ineligibility imposed upon the Covered Person.

Rule 3233. Conditions Precedent to Reinstatement for Covered Horses

(a) A Covered Horse shall be reinstated once its period of Ineligibility ends, provided that (1) the Ineligibility has been respected in full throughout that period in accordance with Rule 3229, (2) the Covered Horse has been made available for Testing during that period in accordance with Rule 3132(d), and (3) the Covered Horse has completed any Vets' List Workout(s) required by the Racetrack Safety Program or the Agency (for the avoidance of doubt, such workouts may be scheduled prior to the expiry of the period of Ineligibility and will not constitute a violation of Rule 3229).

(b) Any reinstatement pursuant to this Rule 3233 is without prejudice to any rest or stand down period that may be imposed on the Covered Horse (*e.g.,* due to injuries), and any requirements for release from the Veterinarians' List, pursuant to the Racetrack Safety Program.

3240. Results Management

Rule 3241. General

Where there is evidence of a potential Anti-Doping Rule Violation(s), the Agency will conduct Results Management in accordance with this section 3240 and the Testing and Investigations Standards.

Rule 3242. Review of Adverse Analytical Findings

(a) Upon receipt of an Adverse Analytical Finding in relation to an A Sample, the Agency will conduct a review of the Laboratory certificate of analysis supporting the Adverse Analytical Finding and the relevant Sample collection documentation and Testing documents to determine whether the Adverse Analytical Finding was caused by any apparent departure from the Testing and Investigations Standards, the Laboratory Standards, or any provision of the Protocol. Subject to Rule 3242(b), the Agency may, but does not have to, communicate with the Responsible Person and Owner during such review.

(b) If the review under Rule 3242(a) reveals an apparent departure that caused the Adverse Analytical Finding, the entire test shall be considered negative, and the Agency shall promptly inform the Responsible Person and each Interested Party of that fact.

(c) If the initial review of an Adverse Analytical Finding under Rule 3242(a) does not reveal an apparent departure that caused the Adverse Analytical Finding, the Agency shall promptly send an EAD Notice to the Responsible Person and each Interested Party in accordance with Rule 3245.

Rule 3243. Review of Atypical Findings Relating to Banned Substances

(a) In certain circumstances, Laboratories may report the presence of certain Banned Substances as ''Atypical Findings'' in accordance with the Atypical Findings Policy set out at Appendix 1. Upon receipt of an A Sample Atypical Finding, the Agency will conduct a review to determine whether the Atypical Finding was caused by a departure from the Testing and Investigations Standards, the Laboratory Standards, or any provision of the Protocol. If that review does not reveal any departure that caused the Atypical Finding, the Agency will conduct an investigation (including directing any Further Analysis) or take any other steps required to decide whether the Atypical Finding should be brought forward as an Adverse Analytical Finding, in accordance with the Atypical Findings Policy.

(b) The Agency may, but does not have to, provide notice of an Atypical Finding to anyone until it has made that decision unless one of the following circumstances exists:

(1) if the Agency determines that the B Sample should be analyzed prior to the conclusion of its investigation, the Agency may conduct the B Sample analysis after notifying the Responsible Person and the Owner, with such notice to include a description of the Atypical Finding and the information described in Rule 3245; or

(2) if the Atypical Finding is likely connected to a serious pathology that requires urgent veterinary attention.

(c) If the Agency ultimately decides not to pursue the Atypical Finding as an Adverse Analytical Finding, the Agency may, but does not have to, communicate that fact to the Responsible Person and Owner unless he or she has previously received notice of the Analytical Finding pursuant to Rule 3243(b).

(d) If the Agency decides to move forward with the matter as an Adverse Analytical Finding, the Agency shall promptly send an EAD Notice to the Responsible Person and each Interested Party.

Rule 3244. Review of Other Evidence of a Potential Anti-Doping Rule Violation

The Agency shall conduct any follow-up investigation required into any potential Anti-Doping Rule Violation not covered by Rules 3242 or 3243. At such time as the Agency is satisfied that it has sufficient evidence to establish that an Anti-Doping Rule Violation occurred, it shall promptly send an EAD Notice to the relevant Covered Person and each Interested Party.

Rule 3245. EAD Notice

(a) Where it is determined that a Covered Person may have committed one or more Anti-Doping Rule Violations, the Agency will promptly notify the Covered Person and each Interested Party in writing of the following (the EAD Notice):

(1) the alleged Anti-Doping Rule Violation and the Consequences if it is agreed or determined to have been committed;

(2) the Adverse Analytical Finding (with a copy of the Laboratory certificate of analysis in a form designated by the Agency) or a brief summary of the facts relied on by the Agency to assert the alleged violation (including, where applicable, the name of the Covered Horse implicated in the alleged violation, whether the alleged violation was in connection with a particular Covered Horserace, and the date of Sample collection or of the other relevant facts said to give rise to the violation);

(3) if applicable, the right of the Responsible Person and the Owner to receive copies of the A Sample Laboratory Documentation Package after the B Sample analysis has been completed or after such analysis is waived;

(4) if applicable, the following details regarding the B Sample analysis:

(i) that the B Sample has been (or will be) analyzed because the Agency has authorized immediate analysis to preserve the scientific integrity of the Sample;

(ii) if the B Sample has not been analyzed, the Responsible Person's and Owner's right to promptly request the analysis of the B Sample within no more than 5 days or (failing such request) that the B sample analysis shall be deemed to be waived;

(iii) an explanation that, where the Responsible Person or Owner requests the B Sample analysis within the applicable deadline, or where the Agency decides to proceed with the B Sample analysis, the Agency will notify

the Responsible Person and Owner of the date, time, and place where the B Sample will be analyzed and (where the analysis is requested by the Responsible Person or Owner) the amount that the Responsible Person or Owner must pay to have the B Sample tested and B Sample Laboratory Documentation Package prepared, and the date by which such payment must be received, failing which the B Sample analysis shall be deemed to have been waived; and

(5) the opportunity for the Covered Person to provide an explanation within a short deadline set by the Agency;

(6) the opportunity to provide Substantial Assistance, to admit the Anti-Doping Rule Violation, or to seek to resolve the matter without a hearing under Rule 3249;

(7) all relevant details relating to any Provisional Suspension (including, if applicable, the possibility to accept a voluntary Provisional Suspension) in accordance with Rule 3247; and

(8) if applicable, the ability for the automatic Disqualification of results to be applied immediately in accordance with Rule 3221(a)(2).

(b) Before sending an EAD Notice, for purposes of Rule 3228, the Agency shall seek to determine whether the Covered Person in question has committed any prior violations under the Protocol.

(c) Any defect in the EAD Notice (including a failure to identify the Covered Horseraces implicated in the alleged violation, if any) may be corrected by the Agency and shall not in any event invalidate the EAD Notice or affect the due application of the provisions of the Protocol (including the Disqualification provisions) in relation to that violation.

Rule 3246. B Sample Analysis

(a) Arrangements shall be made for analysis of the B Sample without undue delay, in accordance with the Protocol and the Laboratory Standards. Subject to Rule 3246(b), the Responsible Person or Owner must pay the costs of the B Sample analysis in advance, but, if the B Sample analysis does not confirm the A Sample analysis, they will be reimbursed that cost by the Agency. The Responsible Person and Owner or one representative each may attend the Laboratory to witness the opening and identification of the B Sample. They do not have any right to witness the analysis of the B Sample.

(b) The Responsible Person and Owner may (if they both agree) waive analysis of the B Sample (in which case they shall be deemed to accept the A Sample analytical results). If waived, the Agency may nonetheless elect to proceed with the B Sample analysis at its own expense.

(c) If the B Sample proves negative, the entire Test shall be considered negative, and the Responsible Person and Owner shall be so informed. In such circumstances, unless the Agency asserts an Anti-Doping Rule Violation under Rule 3213 (Use), the EAD Notice will be withdrawn, any Provisional Suspensions imposed shall be deemed automatically vacated with immediate effect (without the need for any order from the Arbitral Body), and no further disciplinary action will be taken against the Responsible Person, other Covered Person, or Covered Horse by the Agency in relation to the original Adverse Analytical Finding (provided, however, that the Agency may investigate why the B Sample did not match the A Sample). If the Agency asserts that a Rule 3213 (Use) violation has occurred, it shall send a Charge Letter to the Responsible Person and other Covered Person(s), with a copy to each Interested Party.

(d) If the presence of a Banned Substance or the Use of a Banned Method is confirmed by the B Sample analysis, or the B Sample analysis is waived, the Agency shall send a Charge Letter to the Responsible Person and any other relevant Covered Person(s), with a copy to each Interested Party, asserting that a Rule 3212 (presence) violation or a Rule 3213 (Use) violation (as applicable) has occurred.

Rule 3247. Provisional Suspensions

(a) Provisional Suspensions shall be imposed as follows:

(1) For each alleged violation of Rule 3212 (presence), 3213 (Use), or 3214(c) (Administration or Attempted Administration) that involves a Banned Substance that is not a Specified Substance, the Agency shall impose a Provisional Suspension, effective from the date specified by the Agency in the EAD Notice or in further correspondence up to and including the Charge Letter, on (i) the Covered Horse, (ii) the Responsible Person, and (iii) any other Covered Person charged with the violation.

(2) For each alleged violation of Rule 3215 (evading Sample collection; refusing or failing to submit to Sample collection; or refusing or failing to comply with all Sample collection procedure requirements), the Agency may impose a Provisional Suspension, effective from the date specified by the Agency in the EAD Notice or in further correspondence up to and including the Charge Letter, on (i) the Covered Horse, (ii) the Responsible Person, or (iii) any other Covered Person charged with the violation.

(3) For all other alleged Anti-Doping Rule Violations, the Agency may impose a Provisional Suspension, effective from the date specified by the Agency in the EAD Notice or in further correspondence up to and including the Charge Letter, on the Responsible Person, or any other Covered Person alleged to be implicated in the violation, but not on the Covered Horse.

(b) Where a Provisional Suspension is imposed pursuant to Rule 3247(a), the Responsible Person (on his or her own behalf and on behalf of the Covered Horse) and any other Covered Person made subject to the Provisional Suspension shall be given:

(1) an opportunity for a Provisional Hearing before imposition of the Provisional Suspension;

(2) an opportunity for a Provisional Hearing on a timely basis after imposition of the Provisional Suspension; or

(3) an opportunity for an expedited final adjudication in accordance with Rule 3262 on a timely basis after imposition of the Provisional Suspension.

(c) Provisional Hearings shall be conducted by the Arbitral Body and heard via telephone or video conference call within the time frame specified in accordance with the Arbitration Procedures. The sole issue to be determined by the Arbitral Body will be whether the Agency's decision to impose a Provisional Suspension shall be maintained. The Agency's decision to impose a Provisional Suspension shall be maintained unless the Responsible Person/Covered Person requesting the lifting of the Provisional Suspension establishes that:

(1) the allegation that an Anti-Doping Rule Violation has been committed has no reasonable prospect of being upheld, *e.g.,* because of a material defect in the evidence on which the allegation is based;

(2) the Responsible Person/Covered Person charged bears No Fault or Negligence for the Anti-Doping Rule Violation that is alleged to have been committed, so that any period of Ineligibility that might otherwise be imposed for such offense would be completely eliminated by application of Rule 3224. (This ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse);

(3) Rule 3225 applies and the Responsible Person/Covered Person bears No Significant Fault or Negligence and he or she will likely be given a period of Ineligibility that is not longer than the period for which he or she has already been provisionally suspended

(this ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse); or

(4) exceptional circumstances exist that make it clearly unfair, taking into account all of the circumstances of the case, to impose a Provisional Suspension prior to the final hearing on the merits. This ground is to be construed narrowly and applied only in truly exceptional circumstances. For example, the fact that the Provisional Suspension would prevent the Responsible Person, Covered Person, or Covered Horse from participating in a particular Timed and Reported Workout, Covered Horserace, or other activity shall not qualify as exceptional circumstances for these purposes.

(d) If the application is made before the Provisional Suspension comes into effect, the Provisional Suspension will not come into effect pending the decision on the application. If the application is made after the Provisional Suspension has come into effect, the Provisional Suspension will remain in place pending the decision on the application.

(e) If it considers it appropriate to do so on the specific facts of the case, the Agency may lift the Provisional Suspension.

(f) If the application to have a Provisional Suspension not imposed/lifted is not granted, a further application may not be made to lift the Provisional Suspension unless: (i) it is based on new and material evidence that the Responsible Person or other Covered Person was not aware of and could not reasonably have been aware of at the time he or she made the original application; or (ii) there has been some other significant and material change in circumstances since the original application was decided. If the Responsible Person or other Covered Person makes a further application that does not meet either of these requirements, costs may be awarded against him or her.

(g) Voluntary Provisional Suspension.

(1) In all cases where a Responsible Person/Covered Person has been notified of or charged with an Anti-Doping Rule Violation, but no Provisional Suspension has been imposed on him or her or on the Covered Horse, that person may (on his or her own behalf and, if the Responsible Person, on behalf of the Covered Horse) voluntarily accept a Provisional Suspension at any time by written notice to the Agency. A copy of the voluntary Provisional Suspension shall promptly be provided to each Interested Party.

(2) A Provisional Suspension that is voluntarily accepted will have effect (in the same manner as if the Provisional Suspension had been imposed under Rule 3247(a)) from the date that written notice of its acceptance is received by the Agency.

(h) No admission will be inferred, or other adverse inference drawn, from the decision of a Covered Person: (1) not to make an application to lift a Provisional Suspension; or (2) to accept a voluntary Provisional Suspension.

(i) If a Provisional Suspension is imposed or voluntarily accepted, and that Provisional Suspension is respected, then the Responsible Person/Covered Person and Covered Horse in question shall receive a credit for such period of Provisional Suspension against any period of Ineligibility that may ultimately be imposed. If the Responsible Person/Covered Person or Covered Horse does not respect a Provisional Suspension, the Responsible Person/Covered Person or Covered Horse shall receive no credit for any period of Provisional Suspension served. If a period of Ineligibility is served pursuant to a decision that is subsequently subject to review, the Responsible Person/Covered Person or Covered Horse shall receive a credit for such period of Ineligibility served against any period of Ineligibility that may ultimately be imposed on review.

(j) Notwithstanding any other provision in this Rule 3247 or elsewhere in the Protocol, any Provisional Suspension imposed on a Covered Horse will be automatically lifted (without the need for any hearing) if it has been in place for a period equal to the period of Ineligibility specified in the Protocol or Prohibited List.

Rule 3248. Charge Letter

If, after receipt of the Covered Person's explanation, or expiry of the deadline to provide such explanation, the Agency remains satisfied that the Covered Person has committed an Anti-Doping Rule Violation(s), the Agency shall promptly charge the Covered Person with the asserted Anti-Doping Rule Violation(s). In this letter of charge (Charge Letter), which will be copied to each Interested Party, the Agency shall:

(a) set out the Anti-Doping Rule Violation(s) that the Covered Person is charged with having committed;

(b) provide a summary of the relevant facts upon which the charge is based, enclosing a copy of the A Sample Laboratory Documentation Package and (if applicable and if requested) the B Sample Laboratory Documentation Package;

(c) specify the Consequences that will apply if the charge is upheld;

(d) grant a deadline of not more than 7 days from receipt of the Charge Letter (unless otherwise agreed by the Agency) for the Covered Person to either:

(1) admit the Anti-Doping Rule Violation(s) charged and:

(i) accept the Consequences proposed by the Agency, in which case the Agency will issue a decision under Rule 3249(b);

(ii) seek to agree to mitigated Consequences with the Agency pursuant to Rule 3249, failing which the Consequences may still be disputed at a hearing; or

(iii) dispute or seek to mitigate the proposed Consequences at a hearing in accordance with Rule 3261 and the Arbitration Procedures; or

(2) deny the Anti-Doping Rule Violation charged and dispute the proposed Consequences at a hearing in accordance with Rule 3261 and Arbitration Procedures;

(e) indicate that, if the Covered Person does not challenge the Agency's assertion of an Anti-Doping Rule Violation or the proposed Consequences within the prescribed deadline, the Covered Person shall be deemed to have waived his or her right to a hearing, admitted the Anti-Doping Rule Violation(s) charged, and accepted the Consequences specified by the Agency in the Charge Letter (without any mitigation of those Consequences);

(f) give the opportunity to provide Substantial Assistance in accordance with Rule 3226(a); and

(g) provide all relevant details relating to any Provisional Suspensions (including, if applicable, the possibility to accept a voluntary Provisional Suspension) in accordance with Rule 3247.

Rule 3249. Case Resolution Without a Hearing

(a) At any time prior to a final decision under the Arbitration Procedures: (1) the Agency may withdraw a Charge Letter for good cause, in which case any Provisional Suspension will be automatically lifted and (absent the emergence of new information) no further steps will be taken in relation to the violations alleged in the Charge Letter; or (2) the Covered Person may agree to admit the Anti-Doping Rule Violation(s) charged (or any other violation of the Protocol) and accede to specified Consequences consistent with the Protocol. In any such case, an adjudication under the Arbitration Procedures will not be required.

(b) In the event that the Covered Person admits the Anti-Doping Rule Violation(s) charged and accedes to Consequences specified by the Agency (or is deemed to have done so in accordance with Rule 3248(a)(5)), the Agency will (1) promptly issue a final decision confirming the commission of the Anti-Doping Rule Violation(s) and setting out the factual basis for the decision and all of the Consequences to be imposed (including a brief summary of the reasons for any period of Ineligibility imposed, unless doing so could compromise an ongoing investigation or proceeding), and (2) send notice of the decision to each Interested Party. The Agency will also Publicly Disclose the decision (or a summary thereof, at the discretion of the Agency) in accordance with Rule 3620.

(c) In the event that the Agency withdraws the Charge Letter, it will (1) promptly issue a summary decision confirming the withdrawal of the Charge Letter, (2) send notice of the decision to the Covered Person concerned, with a copy to each Interested Party, and (3) Publicly Disclose the decision (or a summary thereof, at the discretion of the Agency) in accordance with Rule 3620.

Rule 3250. Notification Requirements

(a) Notification of Anti-Doping Rule Violations will take place as set out in Rule 3245 and Rule 3248. If at any point after an EAD Notice has been provided the Agency decides not to move forward with the charge, it will notify the Covered Person(s) concerned and each Interested Party of that decision.

(b) Notification to a Covered Person by the Agency, for all purposes of the Protocol, may be accomplished either through actual or constructive notice. Actual notice may be accomplished by any means. Constructive notice shall be deemed to have been given when the information in question is 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 or text message to the Covered Person's most recent email address or mobile telephone number on file with the Authority.

3260. Hearings and Review of Final Decisions

Rule 3261. Hearing Before the Arbitral Body

Where a Covered Person is alleged to have committed an Anti-Doping Rule Violation or to have violated Rule 3229, the Covered Person shall be entitled to a hearing before the Arbitral Body in accordance with the Arbitration Procedures. A copy of the final decision of the Arbitral Body shall be sent to the Covered Person(s) concerned, with a copy to the Agency and each Interested Party. The decision (or a summary thereof, at the discretion of the Agency) shall be Publicly Disclosed as provided in Rule 3620. If an individual case involves allegations that both an Anti-Doping Rule Violation and a Controlled Medication Rule Violation have been committed, the matter shall be referred to and adjudicated by the Arbitral Body in accordance with the Arbitration Procedures.

The Arbitral Body may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Arbitral Body.

Rule 3262. Expedited Hearing

In Anti-Doping Rule Violation cases where the Covered Horse or Covered Person in question is not Provisionally Suspended and is likely to participate in a Covered Horserace within 45 days, the Agency may (if it sees fit) address the case on an expedited basis and shorten any deadlines in the Protocol or Arbitration Procedures proportionately to ensure resolution of the matter prior to the Covered Horserace.

Rule 3263. Finality

Subject to Rule 3264, decisions rendered by the Arbitral Body under the Protocol shall be final and binding.

Rule 3264. Review of Final Decisions

Any final decision by the Agency or the Arbitral Body is subject to review in accordance with section 3058 of the Act. Any final decision under review shall remain in effect pending resolution of the review unless ordered otherwise.

3310. Controlled Medication Rule Violations

Rule 3311. Definition of Controlled Medication Rule Violation and Responsibility for Violations

(a) Controlled medication cases will be initiated based on the assertion that one or more of Rules 3312 through 3315 has been violated (each, a Controlled Medication Rule Violation).

(b) The Controlled Medication Rule Violations described below may only be committed by Covered Persons, but the Consequences for Controlled Medication Rule Violations may apply to both the Covered Person(s) who commit(s) the violation and any Covered Horse(s) implicated by the violation.

(c) All Covered Persons are responsible for knowing what constitutes a Controlled Medication Rule Violation and what Controlled Medication Substances and what Controlled Medication Methods are included on the Prohibited List and Technical Document–Prohibited Substances.

Rule 3312. Presence of a Controlled Medication Substance

(a) It is the personal and non-delegable duty of the Responsible Person to ensure that no Controlled Medication Substance is present in the Post-Race Sample of his or her Covered Horse(s), and that no Controlled Medication Substance specifically identified on the Prohibited List as prohibited during Timed and Reported Workouts is present in the Post-Work Sample of his or her Covered Horse(s). The Responsible Person is therefore strictly liable for any Controlled Medication Substance or its Metabolites or Markers found to be present in a Post-Race Sample collected from his or her Covered Horse(s), and for any specifically prohibited Controlled Medication Substance or its Metabolites or Markers found to be present in a Post-Work Sample collected from his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3312 Controlled Medication Rule Violation.

(b) Sufficient proof of a Rule 3312 Controlled Medication Rule Violation is established by any of the following:

(1) the presence of a Controlled Medication Substance or its Metabolites or Markers in the Covered Horse's A Sample where the Responsible Person waives analysis of the B Sample and the B Sample is not analyzed;

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

(3) where, in exceptional circumstances, the Laboratory (on instruction from the Agency) further splits the A or B Sample into two parts in accordance with the Laboratory Standards, the analysis of the second part of the resulting split Sample confirms the presence of the same Controlled Medication Substance or its Metabolites or Markers as were found in the first part of the split Sample, or the Responsible Person waives analysis of the second part of the split Sample.

(c) The general rule is that the presence of any amount of a Controlled Medication Substance or its Metabolites

or Markers in a Post-Race Sample or Post-Work Sample collected from a Covered Horse constitutes a Controlled Medication Rule Violation by the Responsible Person of that Covered Horse.

(d) As an exception to the general rule of Rule 3312(c), the Prohibited List, Standards, or Technical Documents may establish special criteria for the reporting or the evaluation of certain Controlled Medication Substances, including a Minimum Reporting Level, Screening Limit, Threshold, or Decision Limit.

(e) Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and corticosteroids, which are Controlled Medication Substances prohibited during Timed and Reported Workouts and during the Race Period, are subject to Screening Limits.

(1) If one NSAID or one corticosteroid is detected in the Post-Race Sample or Post-Work Sample of a Covered Horse above the applicable Screening Limit, it constitutes a presence violation under Rule 3312.

(2) If more than one NSAID or more than one corticosteroid is detected in the Post-Race Sample or Post-Work Sample of a Covered Horse, each NSAID and each corticosteroid above the applicable Screening Limit constitutes a separate presence violation of Rule 3312.

(3) If more than one NSAID or more than one corticosteroid is detected in the Post-Race Sample or Post-Work Sample of a Covered Horse, but each are below the applicable Screening Limits (and so individually would not constitute a presence violation), they will together constitute a single presence violation under Rule 3312 (Stacking Violation).

Rule 3313. Use or Attempted Use of a Controlled Medication Substance or a Controlled Medication Method During the Race Period

(a) Subject to Rule 3313(c), the Use or Attempted Use of a Controlled Medication Substance or Controlled Medication Method in relation to a Covered Horse during the Race Period constitutes a Controlled Medication Rule Violation. The success or failure of that Use or Attempted Use is not material. For a Rule 3313 violation to be committed, it is sufficient that the Controlled Medication Substance or Controlled Medication Method was Used or Attempted to be Used on a Covered Horse during the Race Period.

(b) It is the personal and non-delegable duty of the Responsible Person to ensure that no Controlled Medication Substance or Controlled Medication Method is Used in relation to his or her Covered Horse during the Race Period. The Responsible Person is therefore strictly liable for any Use of a Controlled Medication Substance or Controlled Medication Method in relation to his or her Covered Horse(s). Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3313 Controlled Medication Rule Violation of Use. However, in accordance with the definition of Attempt, it is necessary to show intent on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3313 Controlled Medication Rule Violation of Attempted Use.

(c) Use of a Controlled Medication Substance or a Controlled Medication Method outside the Race Period is not a Rule 3313 violation. However, if a Controlled Medication Substance or any of its Metabolites or Markers is still present in a Post-Race Sample or Post-Work Sample, that constitutes a Rule 3312 (presence) violation.

Rule 3314. Use of a Controlled Medication Substance or a Controlled Medication Method in a Manner Contrary to Horse Welfare

(a) Any Use of a Controlled Medication Substance or a Controlled Medication Method in relation to a Covered Horse must (1) be justified by the Covered Horse's health condition(s), (2) have been recommended by a Veterinarian in the context of a valid veterinarian-patient-client relationship or (if a prescription is not required) following sufficient due diligence regarding the substance or method, (3) go no further than the minimum necessary to address the health concerns, and (4) be in the best interests of the Covered Horse's health and welfare.

(b) It is the personal and non-delegable duty of the Responsible Person to ensure that no Controlled Medication Substance or Controlled Medication Method is Used on his or her Covered Horse in breach of the requirements set out in Rule 3314(a). The Responsible Person is therefore strictly liable for a violation of this Rule 3314. Accordingly, it is not necessary to demonstrate intent, Fault, negligence, or knowing Use on the part of the Responsible Person in order to establish that the Responsible Person has committed a Rule 3314 Controlled Medication Rule Violation.

Rule 3315. Other Controlled Medication Rule Violations Involving Controlled Medication Substances or Controlled Medication Methods

The following acts and omissions constitute Controlled Medication Rule Violations by the Covered Person(s) in question:

(a) The Administration or Attempted Administration of a Controlled Medication Substance or Controlled Medication Method by a Covered Person to a Covered Horse during the Race Period.

(b) The Possession of a Controlled Medication Substance or Controlled Medication Method by any Covered Person that is not in compliance with applicable State or Federal law.

(c) A Covered Person assisting, encouraging, aiding, abetting, conspiring, covering up, or engaging in any other type of intentional complicity or Attempted complicity involving (1) a Controlled Medication Rule Violation or Attempted Controlled Medication Rule Violation, or (2) a violation of Rule 3329 by another Covered Person.

Rule 3316. Tampering or Attempted Tampering With Medication Control

If the Agency establishes that a Covered Person committed a violation of Tampering or Attempted Tampering in connection with a Medication Control process, that will constitute an Anti-Doping Rule Violation under Rule 3216(a), and the matter will be dealt with in accordance with the procedures and Consequences applicable to Anti-Doping Rule Violations.

3320. Sanctions

Rule 3321. Disqualification of the Covered Horse's Results

(a) Automatic Disqualification of results.

(1) A Controlled Medication Rule Violation that arises from a Post-Race Sample, or that occurs during the Race Period, automatically leads to Disqualification of the results of the Covered Horse obtained on the Race Day(s) that fall(s) within the Race Period, even if any other sanction for the violation is eliminated or reduced under Rules 3324, 3325, or 3326.

(2) In circumstances where an ECM Notice has been sent as required under Rule 3345, and the B Sample analysis confirms the A Sample analysis, or the right to request the analysis of the B Sample is waived, the Agency, the Responsible Person, and the Owner of the Covered Horse in question may agree to apply Rule 3321 immediately, *i.e.,* prior to adjudication of any other issue, or (in the absence of such

agreement) any one of them may request that the Internal Adjudication Panel apply Rule 3321 immediately.

(b) No Disqualification of subsequent results.

Subsequent results obtained by the Covered Horse from the date a Controlled Medication Rule Violation first occurred through the commencement of any Provisional Suspension or Ineligibility period for the Covered Horse shall not be Disqualified.

(c) Consequence of Disqualification of results.

(1) If a Covered Horse has results Disqualified under the Protocol, all purses and other compensation, prizes, trophies, points, and rankings are forfeited and must be repaid or surrendered (as applicable) to the Race Organizer, and the results of the other Covered Horses in the race(s) in question must be adjusted accordingly and the purses, prizes, and trophies redistributed. Purses, prizes, trophies, and other compensation shall (where possible) be withheld for the Covered Horse in issue pending resolution of the relevant charge.

(2) The Covered Horses that participated in a Covered Horserace involving an alleged Controlled Medication Rule Violation are often entered in other Covered Horseraces prior to the final adjudication of the violation. The ultimate Disqualification of a Covered Horse in connection with final adjudication of a violation shall only impact that horse's conditions for eligibility. By way of example, a maiden that is Disqualified after finishing first in a maiden race shall remain a maiden until it has won another race, but the runner-up in the disputed Covered Horserace shall not be considered the winner for purposes of its future condition eligibility. The adjustment to the Disqualified horse's condition eligibility shall only occur once the violation has been finally adjudicated.

Rule 3322. Ineligibility for Covered Horses

(a) There shall be no period of Ineligibility for Covered Horses implicated in violations involving only Controlled Medication Substances.

(b) There may be a period of Ineligibility for Covered Horses implicated in violations involving Controlled Medication Methods. Where the Prohibited List specifies a period of Ineligibility, it shall be applied only prospectively (*i.e.,* going forward from the date that it is imposed), with no Disqualification of any results obtained by the Covered Horse before the date that the period of Ineligibility starts to run, other than as provided under Rule 3321(a)(1).

Rule 3323. Ineligibility and Financial Penalties for Covered Persons

(a) General.

(1) The periods of Ineligibility and financial penalties set out in this Rule 3323 apply to any Controlled Medication Rule Violation committed by a Covered Person. However:

(i) When determining if a Covered Person has committed multiple violations, the following prior Controlled Medication Rule Violations shall be disregarded: (A) violations that occurred more than 2 years prior to the violation now being sanctioned; and (B) violations for which the Covered Person was found to bear No Fault or Negligence.

(ii) A Controlled Medication Rule Violation will be considered a second or subsequent violation only if the Covered Person committed an offense in the same category/class in the previous 2 years. Violations in different categories will be taken into account when assigning penalty points under Rule 3328.

(iii) Unless specified otherwise, the periods of Ineligibility set out in this Rule 3323 are subject to potential elimination, reduction, or suspension pursuant to Rules 3324–3326, or increase pursuant to Rule 3327.

(2) In accordance with Rule 3347(j), any period of Provisional Suspension served by the Covered Person shall be credited against the period of Ineligibility ultimately imposed on that Covered Person for the violation in question.

(3) If a presence violation involves a Controlled Medication Substance that has not been assigned a Class A–C, the Agency shall determine the class of the substance. Any supplements or feed additives used in contravention of Rule 4211(a) of the Prohibited List that have not been assigned a class shall be designated as Class C substances, unless the Agency decides otherwise.

(4) If two or more Controlled Medication Rule Violations in the same category/class are adjudicated separately, the first violation adjudicated shall constitute the ''first violation'' for sanctioning purposes, the second violation adjudicated shall constitute the ''second violation,'' and so on, regardless of the chronological order in which those violations occurred.

(b) Consequences.

Subject to Rule 3323(a), and in addition to any other Consequences that apply under the Protocol, the periods of Ineligibility, fines, and Disqualification of results specified below shall apply to any Covered Person who commits multiple Controlled Medication Rule Violations. The Covered Person may also be required to pay some or all of the adjudication costs and the Agency's legal costs.

Controlled medication rule violation	First violation (within 2-year period)	Second violation (within 2-year period)	Third or subsequent violation (within 2-year period)
Presence, Use or Attempted Use, or Administration or Attempted Administration of a Controlled Medication Substance (Rules 3312, 3313, and 3315(a)):			
Class A	60 days	90 days	120 days.
	Fine of up to $5,000 or 5% of the total purse (whichever is greater).	Fine of up to $10,000 or 10% of the total purse (whichever is greater).	Fine of up to $25,000 or 25% of the total purse (whichever is greater).
	Automatic Disqualification of Race Day results (Rule 3321).	Automatic Disqualification of Race Day results (Rule 3321).	Automatic Disqualification of Race Day results (Rule 3321).
Class B	15 days	30 days	60 days.
	Fine up to $1,000	Fine up to $2,500	Fine up to $5,000.
	Automatic Disqualification of Race Day results (Rule 3321).	Automatic Disqualification of Race Day results (Rule 3321).	Automatic Disqualification of Race Day results (Rule 3321).

Controlled medication rule violation	First violation (within 2-year period)	Second violation (within 2-year period)	Third or subsequent violation (within 2-year period)
Class C	..... Fine up to $500 Automatic Disqualification of Race Day results (Rule 3321).	15 days Fine up to $1,000 Automatic Disqualification of Race Day results (Rule 3321).	30 days. Fine up to $2,500. Automatic Disqualification of Race Day results (Rule 3321).
Note: Sanctions apply for each Controlled Medication Substance detected in the Sample. A Stacking Violation shall be treated as a single violation for the purposes of sanctions.			
Use or Attempted Use or Administration or Attempted Administration of a Controlled Medication Method (Rule 3313).	60 days Fine of up to $5,000 or 5% of the total purse (whichever is greater). Automatic Disqualification of Race Day results (Rule 3321).	90 days Fine of up to $10,000 or 10% of the total purse (whichever is greater). Automatic Disqualification of Race Day results (Rule 3321).	120 days. Fine of up to $25,000 or 25% of the total purse (whichever is greater). Automatic Disqualification of Race Day results (Rule 3321).
Use of a Controlled Medication Substance or a Controlled Medication Method in a manner contrary to horse welfare (Rule 3314).	60 days Fine of up to $5,000 or 5% of the total purse (whichever is greater).	90 days Fine of up to $10,000 or 10% of the total purse (whichever is greater).	120 days. Fine of up to $25,000 or 25% of the total purse (whichever is greater).
Possession of a Controlled Medication Substance/Method that is not in compliance with applicable state or Federal law (Rule 3315(b)).	..... Fine up to $500 Referral to the relevant State or Federal authority.	15 days Fine up to $1,000 Referral to the relevant State or Federal authority.	30 days. Fine up to $2,500. Referral to the relevant State or Federal authority.
Complicity or Attempted complicity (Rule 3315(c)).	Same Consequences that apply to the principal actor, absent mitigating or aggravating circumstances.	Same Consequences that apply to the principal actor, absent mitigating or aggravating circumstances.	Same Consequences that apply to the principal actor, absent mitigating or aggravating circumstances.

(c) Commencement of the period of Ineligibility for a Covered Person.

(1) Except as otherwise provided in this Rule 3323, the period of Ineligibility imposed on any Covered Person shall start on the date the period of Ineligibility is accepted or otherwise imposed in accordance with the Protocol.

(2) Where a Covered Person is already serving a period of Ineligibility for another violation of the Protocol, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends.

(3) Where there have been substantial delays in the adjudication process or other aspects of Medication Control that go well beyond the standard timeframes for Laboratory analyses and Results Management, and the Covered Person can establish that such delays are not attributable to him or her, the start date of the period of Ineligibility may be deemed back-dated to reflect such delays, but in no event may it be deemed back-dated to a date before the Controlled Medication Rule Violation last occurred.

(d) Additional rules for certain multiple violations.

(1) Multiple violations for the same Controlled Medication Substance/Method incurred by a Covered Person in relation to the same Covered Horse prior to delivery of an ECM Notice may (at the Agency's discretion) be treated together as a single Controlled Medication Rule Violation, unless the facts demonstrate that there was more than one administration. Multiple violations for the same Controlled Medication Substance/Method incurred by a Covered Person in relation to different Covered Horses prior to delivery of an ECM Notice may each be treated as a first Controlled Medication Rule Violation within the relevant category/class. Where multiple Controlled Medication Substances are detected in a single Post-Race Sample or Post-Work Sample, each Controlled Medication Substance may be treated as a separate violation and assigned separate penalty points.

(2) If the Agency establishes that prior to receiving an ECM Notice in respect of one Controlled Medication Rule Violation the Covered Person committed an additional Controlled Medication Rule Violation that occurred 12 months or more before or after the violation asserted in that ECM Notice, the period of Ineligibility for the additional violation shall be calculated as if the additional violation were a stand-alone first violation, and that period of Ineligibility will run consecutively to (rather than concurrently with) the period of Ineligibility imposed for the first-notified violation. Where this Rule applies, the violations taken together will constitute a single violation for purposes of Rule 3323(b).

(3) If the Agency establishes that the Covered Person has committed a further violation of the Protocol during a period of Ineligibility, any new period of Ineligibility shall start to run the day after the original period of Ineligibility ends.

(e) Violations involving both a Banned Substance or Method and a Controlled Medication Substance or Method.

Where a Covered Person is found, based on a common set of facts, to have committed a (1) violation involving one or more Banned Substance(s) or Banned Method(s), and (2) a violation involving one or more Controlled Medication Substance(s) or Controlled Medication Method(s), they shall be treated as separate violations, but shall be adjudicated together in consolidated proceedings pursuant to the procedure that applies to Anti-Doping Rule Violations under the Arbitration Procedures.

Rule 3324. Elimination of the Period of Ineligibility Where There Is No Fault or Negligence

(a) If a Covered Person establishes in an individual case that he or she bears No Fault or Negligence for the Controlled Medication Rule Violation(s) charged, the otherwise applicable period of Ineligibility and other Consequences for such Covered Person shall be eliminated (except for those set out in Rule 3321 and Rule 3620). When the violation is of Rule 3312 (presence of a Controlled Medication Substance), the Covered Person must also establish how the Controlled Medication Substance entered the Covered Horse's

system as a pre-condition to application of this Rule 3324. In the event the period of Ineligibility otherwise applicable is eliminated pursuant to this Rule 3324, the Controlled Medication Rule Violation shall not be considered a prior violation for the purpose of Rule 3323(b).

(b) Rule 3324 only applies in exceptional circumstances. In particular, it will not apply where the Controlled Medication Substance found to be present in a Sample: (1) came from a mislabeled or contaminated supplement; or (2) was administered to the Covered Horse by veterinary or other support personnel without the knowledge of the Responsible Person.

(c) A finding that the Covered Person bears No Fault or Negligence for a Controlled Medication Rule Violation shall not affect the Consequences of that violation that apply to the Covered Horse (*i.e.,* Ineligibility in accordance with Rule 3322(b) and Disqualification of results in accordance with Rule 3321).

Rule 3325. Reduction of the Period of Ineligibility Where There Is No Significant Fault or Negligence (Limited to Class A/B or Equivalent)

This Rule applies only to Controlled Medication Rule Violations involving Class A or Class B substances or a category of violation with sanctions equivalent to Class A or Class B substances. Reductions under this Rule 3325 are mutually exclusive and not cumulative, *i.e.,* no more than one of them may be applied in a particular case.

(a) General rule.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Controlled Medication Rule Violation in question, then (unless Rule 3325(b) or 3325(c) applies) the period of Ineligibility may be reduced, depending on the Covered Person's degree of Fault, but the reduced period of Ineligibility may not be less than one-half of the otherwise applicable period of Ineligibility.

(b) Specified Substances.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Controlled Medication Rule Violation in question, and the violation involves only a Specified Substance, the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, the otherwise applicable period of Ineligibility, depending on the Covered Person's degree of Fault.

(c) Contaminated Products or other contamination.

Where the Covered Person establishes that he or she bears No Significant Fault or Negligence for the Controlled Medication Rule Violation in question and that the Controlled Medication Substance in question came from a Contaminated Product or from another form of contamination, the period of Ineligibility shall be, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, the otherwise applicable period of Ineligibility, depending on the Covered Person's degree of Fault.

Rule 3326. Elimination, Reduction, or Suspension of Period of Ineligibility or Other Consequences for Reasons Unrelated to Degree of Fault

(a) Substantial Assistance. The Agency may suspend all or part of the Consequences imposed on a Covered Person in an individual Controlled Medication Rule Violation case—other than Disqualification of results pursuant to Rule 3321—based on the following:

(1) The Covered Person provides Substantial Assistance to the Agency, the Authority, or a State Racing Commission, a criminal authority, or a professional disciplinary body that results in:

(i) the Agency discovering or bringing forward an Anti-Doping Rule Violation or a Controlled Medication Rule Violation by another Covered Person; or

(ii) 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 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 also made available to the Agency.

(2) The extent to which the otherwise applicable period of Ineligibility may be suspended shall be based on the seriousness of the Controlled Medication Rule Violation committed by the Covered Person and the degree to which the Substantial Assistance provided by the Covered Person assists the effort to promote doping-free racing, compliance with the Protocol, or the integrity of racing. In any event, no more than three-quarters of the otherwise applicable period of Ineligibility may be suspended. For purposes of this Rule 3326, the otherwise applicable period of Ineligibility shall not include any period of Ineligibility that could be added under Rule 3323(d)(2).

(3) If so requested, the Agency shall allow the Covered Person who seeks to provide Substantial Assistance to provide the information to the Agency subject to a Without Prejudice Agreement.

(4) If the Covered Person fails to continue to cooperate or fails to provide the complete, accurate, and credible Substantial Assistance promised, the Agency shall reinstate the original Consequences. That decision is not subject to review.

(b) Voluntary Admission of a Controlled Medication Rule Violation in the absence of other evidence. If (1) the Covered Person voluntarily admits the commission of a Controlled Medication Rule Violation before receiving the ECM Notice or (in the case of a Rule 3312 violation) before having received notice of a Sample collection that could establish the Controlled Medication Rule Violation, and (2) that admission is the only reliable evidence of the violation at the time the admission is made, the otherwise applicable period of Ineligibility may be reduced by up to one-half.

(c) Application of multiple grounds for reduction of a sanction. If the Covered Person establishes entitlement to a reduction or suspension of the period of Ineligibility under 2 or more of Rules 3324, 3325, or 3326, the otherwise applicable period of Ineligibility shall be determined in accordance with Rules 3323, 3324, and 3325 before applying any reduction or suspension under Rule 3326. If the Covered Person establishes entitlement to a reduction or suspension of the period of Ineligibility under Rule 3326, up to three-quarters of the otherwise applicable period of Ineligibility may be reduced or suspended.

(d) Reductions for certain Controlled Medication Rule Violations based on early admission and acceptance of sanction. If the Covered Person admits the violation and accepts the asserted period of Ineligibility no more than 7 days after receiving the Charge Letter, the period of Ineligibility to be served will be automatically reduced by one-half (but no further reduction shall be allowed under any other Rule).

Rule 3327. Aggravating Circumstances

(a) If the Agency establishes in an individual Controlled Medication Rule Violation case that Aggravating Circumstances are present, the period of Ineligibility otherwise applicable shall be increased by up to 6 months depending on the seriousness of the Aggravating Circumstances, unless the Covered Person establishes that he or she did not knowingly commit the Controlled Medication Rule Violation. Where the period of Ineligibility is increased pursuant to this Rule, an

additional fine of up to $5,000 or an additional 5% of the total purse (whichever is greater) may also be imposed.

(b) Actions and circumstances constituting Aggravating Circumstances include:

(1) Administration of a Controlled Medication Substance or Use of a Controlled Medication Method that is detrimental to the health and welfare of the horse or is designed to deceive the betting public;

(2) prior violations under the Protocol; or

(3) the Covered Person engaged in deceptive or obstructive conduct to avoid the detection or adjudication of a Controlled Medication Rule Violation, for which the Covered Person has not been separately sanctioned for Tampering.

(c) For the avoidance of doubt, the examples set out in Rule 3327(b) are not exhaustive and other similar circumstances or conduct may also be deemed to amount to Aggravating Circumstances that justify the imposition of a longer period of Ineligibility.

Rule 3328. Penalty Points System for Multiple Controlled Medication Rule Violations

(a) The penalty points system established in this Rule 3328 does not replace or lessen in any way the Consequences that apply to the underlying Controlled Medication Rule Violation. Rather, the penalty points system is intended to apply additional uniform Consequences where the Covered Person is a repeat offender and exceeds the permissible number of points.

(b) Covered Persons shall be assigned penalty points as set out in the table below for each Controlled Medication Rule Violation that they commit. The imposition of the specified penalty points is automatic, without any consideration of mitigating or aggravating circumstances, except that:

(1) no points shall be assigned for any violations (i) where the Covered Person was found to bear No Fault or Negligence, or (ii) resulting from environmental contamination;

(2) fewer or no points may be assigned where the Covered Person provides Substantial Assistance in accordance with Rule 3326; and

(3) the penalty points for a complicity or Attempted complicity violation may be adjusted if there are mitigating or aggravating circumstances.

Controlled medication rule violation	Penalty points
Presence, Use or Attempted Use, or Administration or Attempted Administration of a Controlled Medication Substance:	
Class A	3.
Class B	2.
Class C	1½.
Note: Points are assigned for each Controlled Medication Substance detected in the Sample. A Stacking Violation shall be treated as a single violation.	
Use of a Controlled Medication Substance or a Controlled Medication Method in a manner contrary to horse welfare.	3.
Use or Attempted Use or Administration or Attempted Administration of a Controlled Medication Method.	3.
Possession of a Controlled Medication Substance or Controlled Medication Method that is not in compliance with applicable state or Federal law.	1.
Complicity or Attempted complicity in a Controlled Medication Rule Violation committed by another Person.	Same number of points that apply to the Responsible Person, absent mitigating or aggravating circumstances.
Violation of Rule 3329	Same number of points as were assigned for the underlying violation.

(c) In addition to the Consequences applicable to the underlying Controlled Medication Rule Violation, the following Consequences shall be imposed based on the cumulative points contained in the Covered Person's official record:

Cumulative penalty points	Additional period of ineligibility
6–7	30 days.
7.5–9	60 days.
9.5–12	90 days.
12.5 or more	180 days.

(d) Penalty points and the additional period of Ineligibility shall be applied automatically at the conclusion of the proceeding on the underlying violation, without any additional hearing or right of review. Penalty points shall be applied retroactively to start on the date on which the Controlled Medication Rule Violation occurred and shall expire after 2 years.

(e) The additional period of Ineligibility imposed based on penalty points shall run consecutive to any period of Ineligibility imposed for the underlying Controlled Medication Rule Violation.

(f) A Covered Person's official record of cumulative penalty points shall be maintained by the Agency.

Rule 3329. Status During Provisional Suspension or Ineligibility

(a) While serving a Provisional Suspension or period of Ineligibility for a Controlled Medication Rule Violation:

(1) a Covered Horse may not participate in any Timed and Reported Workout or Covered Horserace, but shall remain subject to Testing;

(2) a Covered Person may not participate in any capacity in any activity involving Covered Horses, or in any other activity (other than authorized anti-doping education or rehabilitation programs) taking place at a Racetrack or Training Facility, nor shall he or she permit anyone to participate in any capacity on his or her behalf in any such activities, except to the extent that the Covered Person is an Owner and the activity is necessary to ensure the safekeeping and wellbeing of the horse during the period of such Owner's Provisional Suspension or Ineligibility.

(b) The Covered Horse(s) of an Owner or Trainer who is subject to a Provisional Suspension or period of Ineligibility shall be subject to the following restrictions:

(1) The Covered Horse(s) of a Trainer who is subject to a Provisional Suspension or period of Ineligibility

may not participate in any Timed and Reported Workout or Covered Horserace unless and until they have been transferred to another Covered Person, except that such Covered Horses may participate in a Covered Horserace if they were entered in the race before the Trainer was notified of the Provisional Suspension or the period of Ineligibility was imposed or accepted (whichever is earlier). For the ''transfer'' to be valid, (i) the transfer must be registered with the Authority in accordance with its procedures, and (ii) if the Trainer is subject to a period of Ineligibility of more than 30 days, the Covered Horses must also be physically relocated to facilities under the care or control of a Covered Person who is not affiliated with the suspended Trainer (and failure to comply may constitute an Anti-Doping Rule Violation under Rule 3216(c), *i.e.,* Prohibited Association).

(2) The Covered Horse(s) of an Owner who is subject to a Provisional Suspension or period of Ineligibility may not participate in any Timed and Reported Workout or Covered Horserace unless and until they have been transferred in a bona fide transaction to a different Owner. If an Immediate Family Member has any ownership or property interest in the Covered Horse(s) following such transfer, the transfer shall not constitute a bona fide transaction to a different Owner.

Rule 3330. Consequences for Violation of the Prohibition on Participation During Ineligibility or Provisional Suspension Under Rule 3329

(a) Consequences for violation of the prohibition on participation during Ineligibility.

(1) If a Covered Person violates the prohibition against participation during Ineligibility described in Rule 3329, any results obtained from 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 Covered Person's original period of Ineligibility.

(2) If a Covered Horse participates in any Timed and Reported Workout or Covered Horserace in violation of the prohibition against participation during Ineligibility described in Rule 3329, any results obtained from such participation shall be Disqualified, and the Responsible Person for that Covered Horse shall receive the following period of Ineligibility:

(i) if the Responsible Person was subject to an original period of Ineligibility, 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. If the original period of Ineligibility has already expired, the new period of Ineligibility shall start on the date that it is accepted or imposed; or

(ii) if the Responsible Person was not subject to an original period of Ineligibility, the period of Ineligibility for violating Rule 3329 shall be from a reprimand to 1 year, depending on the Covered Person's degree of Fault.

(b) Consequences for violation of the prohibition on participation during Provisional Suspension.

(1) A Covered Person who violates the prohibition against participation during a Provisional Suspension shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

(2) If a Covered Horse participates in any Timed and Reported Workout or Covered Horserace in violation of the prohibition against participation during a Provisional Suspension described in Rule 3329, the Responsible Person for that Covered Horse and the Covered Horse shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

(c) The consequence of Disqualification under this Rule 3330 shall be the same as set out in Rule 3321(c).

(d) The Internal Adjudication Panel (or the Agency, if the Covered Person admits the violation and accepts the consequences) shall determine whether there has been a violation of the prohibition against participation during Provisional Suspension or Ineligibility and apply the appropriate consequences pursuant to Rule 3361.

Rule 3331. Automatic Public Disclosure

A mandatory part of each sanction shall include automatic Public Disclosure in accordance with Rule 3620.

Rule 3332. Conditions Precedent to Reinstatement for Covered Persons

(a) To be reinstated after commission of a Controlled Medication Rule Violation, the Covered Person must have respected his or her period of Ineligibility (Rule 3329); and repaid or surrendered any purses and other compensation, prizes, trophies, points, and rankings forfeited pursuant to Rule 3321, and paid any fines and reimbursed any costs imposed or accepted to the Agency, unless an installment plan was established pursuant to Rule 3332(b), in which case the Covered Person must have made all payments due under that plan. If any installment(s) subsequently become(s) overdue under that plan (*i.e.,* after reinstatement), the Covered Person and the Covered Horses under his or her ownership or training may not participate in any Timed and Reported Workout or Covered Horserace until such overdue installment(s) is/are paid in full.

(b) Where fairness requires, the Agency or the Internal Adjudication Panel may establish an installment plan for repayment of amounts due to be paid or reimbursed under the Protocol. The payment schedule may extend beyond any period of Ineligibility imposed upon the Covered Person.

Rule 3333. Conditions Precedent to Reinstatement for Covered Horses

(a) A Covered Horse shall be reinstated once its period of Ineligibility ends, provided that (1) the Ineligibility has been respected in full throughout that period in accordance with Rule 3329, (2) the Covered Horse has been made available for Testing during that period in accordance with Rule 3132(d), and (3) the Covered Horse has completed any Vets' List Workout(s) required by the Racetrack Safety Program or the Agency (for the avoidance of doubt, such workouts may be scheduled prior to the expiry of the period of Ineligibility and will not constitute a violation of Rule 3329).

(b) Any reinstatement pursuant to this Rule 3333 is without prejudice to any rest or stand down period that may be imposed on the Covered Horse (*e.g.,* due to injuries), and any requirements for release from the Veterinarians' List, pursuant to the Racetrack Safety Program.

3340. Results Management

Rule 3341. General

Where there is evidence of a potential Controlled Medication Rule Violation(s), the Agency will conduct Results Management in accordance with this section 3340 and the Testing and Investigations Standards.

Rule 3342. Review of Adverse Analytical Findings

(a) Upon receipt of an Adverse Analytical Finding in relation to an A Sample, the Agency will conduct a review of the Laboratory certificate of analysis supporting the Adverse Analytical Finding and the relevant Sample collection documentation and Testing documents to determine whether the Adverse Analytical Finding was caused by any apparent departure from the Testing and Investigations Standards, the Laboratory Standards, or any provision of the Protocol. Subject to

Rule 3342(b), the Agency may, but does not have to, communicate with the Responsible Person and Owner during such review.

(b) If the review under Rule 3342(a) reveals an apparent departure that caused the Adverse Analytical Finding, the entire test shall be considered negative, and the Agency shall promptly inform the Responsible Person and each Interested Party of that fact.

(c) If the initial review of an Adverse Analytical Finding under Rule 3342(a) does not reveal an apparent departure that caused the Adverse Analytical Finding, the Agency shall promptly send an ECM Notice to the Responsible Person and each Interested Party in accordance with Rule 3345.

Rule 3343. Review of Atypical Findings Relating to Controlled Medication Substances

(a) In certain circumstances, Laboratories may report the presence of certain Controlled Medication Substances as ''Atypical Findings'' in accordance with the Atypical Findings Policy set out at Appendix 1. Upon receipt of an A Sample Atypical Finding, the Agency will conduct a review to determine whether the Atypical Finding was caused by a departure from the Testing and Investigations Standards, the Laboratory Standards, or any provision of the Protocol. If that review does not reveal any departure that caused the Atypical Finding, the Agency will conduct an investigation (including directing any Further Analysis) or take any other steps required to decide whether the Atypical Finding should be brought forward as an Adverse Analytical Finding, in accordance with the Atypical Findings Policy.

(b) The Agency may, but does not have to, provide notice of an Atypical Finding to anyone until it has made that decision unless one of the following circumstances exists:

(1) if the Agency determines that the B Sample should be analyzed prior to the conclusion of its investigation, the Agency may conduct the B Sample analysis after notifying the Responsible Person and the Owner, with such notice to include a description of the Atypical Finding and the information described in Rule 3345; or

(2) if the Atypical Finding is likely connected to a serious pathology that requires urgent veterinary attention.

(c) If the Agency ultimately decides not to pursue the Atypical Finding as an Adverse Analytical Finding, the Agency may, but does not have to, communicate that fact to the Responsible Person and Owner unless he or she has previously received notice of the Analytical Finding pursuant to Rule 3343(b).

(d) If the Agency decides to move forward with the matter as an Adverse Analytical Finding, the Agency shall promptly send an ECM Notice to the Responsible Person and each Interested Party.

Rule 3344. Review of Other Evidence of a Potential Controlled Medication Rule Violation

The Agency shall conduct any follow-up investigation required into any potential Controlled Medication Rule Violation not covered by Rules 3342 or 3343. At such time as the Agency is satisfied that it has sufficient evidence to establish that a Controlled Medication Rule Violation occurred, it shall promptly send an ECM Notice to the relevant Covered Person and each Interested Party.

Rule 3345. ECM Notice

(a) Where it is determined that a Covered Person may have committed one or more Controlled Medication Rule Violations, the Agency will promptly notify the Covered Person and each Interested Party in writing of the following (the ECM Notice):

(1) the alleged Controlled Medication Rule Violation and the Consequences if it is agreed or determined to have been committed;

(2) the Adverse Analytical Finding (with a copy of the Laboratory certificate of analysis in a form designated by the Agency) or a brief summary of the facts relied on by the Agency to assert the alleged violation (including, where applicable, the name of the Covered Horse implicated in the alleged violation, whether the alleged violation was in connection with a particular Covered Horserace, and the date of Sample collection or of the other relevant facts said to give rise to the violation);

(3) if applicable, the right of the Responsible Person and the Owner to receive copies of the A Sample Laboratory Documentation Package after the B Sample analysis has been completed or after such analysis is waived;

(4) if applicable, the following details regarding the B Sample analysis:

(i) that the B Sample has been (or will be) analyzed because the Agency has authorized immediate analysis to preserve the scientific integrity of the Sample;

(ii) if the B Sample has not been analyzed, the Responsible Person's and Owner's right to promptly request the analysis of the B Sample within no more than 5 days or (failing such request) that the B sample analysis shall be deemed to be waived;

(iii) an explanation that where the Responsible Person or Owner requests the B Sample analysis within the applicable deadline, or where the Agency decides to proceed with the B Sample analysis, the Agency will notify the Responsible Person and Owner of the date, time, and place where the B Sample will be analyzed and (where the analysis is requested by the Responsible Person or Owner) the amount that the Responsible Person or Owner must pay to have the B Sample tested and B Sample Laboratory Documentation Package prepared, and the date by which such payment must be received, failing which the B Sample analysis shall be deemed to have been waived; and

(5) the opportunity for the Covered Person to provide an explanation within a short deadline set by the Agency;

(6) the opportunity to provide Substantial Assistance, to admit the Anti-Doping Rule Violation, or to seek to resolve the matter without a hearing under Rule 3349;

(7) all relevant details relating to any Provisional Suspension (including, if applicable, the possibility to accept a voluntary Provisional Suspension) in accordance with Rule 3347; and

(8) if applicable, the ability for the automatic Disqualification of results to be applied immediately in accordance with Rule 3321(a)(2).

(b) Before sending an ECM Notice, for purposes of Rule 3323, the Agency shall seek to determine whether the Covered Person in question has committed any prior violations under the Protocol.

(c) Any defect in the ECM Notice (including a failure to identify the Covered Horseraces implicated in the alleged violation, if any) may be corrected by the Agency and shall not in any event invalidate the ECM Notice or affect the due application of the provisions of the Protocol (including the Disqualification provisions) in relation to that violation.

Rule 3346. B Sample Analysis

(a) Arrangements shall be made for analysis of the B Sample without undue delay, in accordance with the Protocol and the Laboratory Standards. Subject to Rule 3346(b), the Responsible Person or Owner must pay the costs of the B Sample analysis in advance, but, if the B Sample analysis does not confirm the A Sample analysis, they will be reimbursed that cost by the Agency. The Responsible Person and Owner or one representative each may attend the Laboratory to witness the opening and identification of the B Sample. They do

not have any right to witness the analysis of the B Sample.

(b) The Responsible Person and Owner may (if they both agree) waive analysis of the B Sample (in which case they shall be deemed to accept the A Sample analytical results). If waived, the Agency may nonetheless elect to proceed with the B Sample analysis at its own expense.

(c) If the B Sample proves negative, the entire Test shall be considered negative, and the Responsible Person and Owner shall be so informed. In such circumstances, unless the Agency asserts a Controlled Medication Rule Violation under Rules 3313 or 3314 (Use), the ECM Notice will be withdrawn, any Provisional Suspensions imposed shall be deemed automatically vacated with immediate effect (without the need for any order from the Internal Adjudication Panel), and no further disciplinary action will be taken against the Responsible Person, other Covered Person, or Covered Horse by the Agency in relation to the original Adverse Analytical Finding (provided, however, that the Agency may investigate why the B Sample did not match the A Sample). If the Agency asserts that a Rule 3313 or 3314 (Use) violation has occurred, it shall send a Charge Letter to the Responsible Person and other Covered Person(s), with a copy to each Interested Party.

(d) If the presence of a Controlled Medication Substance or the Use of a Controlled Medication Method is confirmed by the B Sample analysis, or the B Sample analysis is waived, the Agency shall send a Charge Letter to the Responsible Person and any other relevant Covered Person(s), with a copy to each Interested Party, asserting that a Rule 3312 (presence) violation or a Rule 3313 (Use) violation (as applicable) has occurred.

Rule 3347. Provisional Suspensions

(a) The Agency shall not impose a Provisional Suspension on a Covered Horse for a Controlled Medication Rule Violation, unless the violation involves a Controlled Medication Method for which the Prohibited List specifies a period of Ineligibility.

(b) The Agency may impose a Provisional Suspension on a Covered Person for a Controlled Medication Rule Violation where it considers it appropriate to do so in the circumstances of the case, including where (1) the Covered Person admits the Controlled Medication Rule Violation and is likely to be subject to a period of Ineligibility, (2) there is an Adverse Analytical Finding for more than one Controlled Medication Substance and those substances are not Specified Substances, (3) the Covered Person has a pending Anti-Doping Rule Violation or Controlled Medication Rule Violation or prior violation that is likely to result in an increased period of Ineligibility, or (4) the individual represents a threat to the health, safety, or welfare of horses or the integrity of the sport of horseracing.

(c) Where a Provisional Suspension is imposed pursuant to Rule 3347(a) or (b), the Responsible Person (on his or her own behalf and on behalf of the Covered Horse) and any other Covered Person made subject to the Provisional Suspension shall be given:

(1) an opportunity for a Provisional Hearing before imposition of the Provisional Suspension;

(2) an opportunity for a Provisional Hearing on a timely basis after imposition of the Provisional Suspension; or

(3) an opportunity for an expedited final adjudication in accordance with Rule 3362 on a timely basis after imposition of the Provisional Suspension.

(d) Provisional Hearings shall be conducted by the Internal Adjudication Panel and heard via telephone or video conference call within the time frame specified in accordance with the Arbitration Procedures, except where the Internal Adjudication Panel decides to determine the matter based solely on the written submissions without a hearing. The sole issue to be determined by the Internal Adjudication Panel will be whether the Agency's decision to impose a Provisional Suspension shall be maintained. The Agency's decision to impose a Provisional Suspension shall be maintained unless the Responsible Person/Covered Person requesting the lifting of the Provisional Suspension establishes that:

(1) the allegation that a Controlled Medication Rule Violation has been committed has no reasonable prospect of being upheld, *e.g.,* because of a material defect in the evidence on which the allegation is based;

(2) the Responsible Person/Covered Person charged bears No Fault or Negligence for the Controlled Medication Rule Violation that is alleged to have been committed, so that any period of Ineligibility that might otherwise be imposed for such offense would be completely eliminated by application of Rule 3324. (This ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse);

(3) Rule 3325 applies and the Responsible Person/Covered Person bears No Significant Fault or Negligence and he or she will likely be given a period of Ineligibility that is not longer than the period for which he or she has already been provisionally suspended. (This ground does not apply in respect of any Provisional Suspension imposed on a Covered Horse); or

(4) exceptional circumstances exist that make it clearly unfair, taking into account all of the circumstances of the case, to impose a Provisional Suspension prior to the final hearing on the merits. This ground is to be construed narrowly and applied only in truly exceptional circumstances. For example, the fact that the Provisional Suspension would prevent the Responsible Person, Covered Person, or Covered Horse from participating in a particular Timed and Reported Workout, Covered Horserace, or other activity shall not qualify as exceptional circumstances for these purposes.

(e) If the application is made before the Provisional Suspension comes into effect, the Provisional Suspension will not come into effect pending the decision on the application. If the application is made after the Provisional Suspension has come into effect, the Provisional Suspension will remain in place pending the decision on the application.

(f) If it considers it appropriate to do so on the specific facts of the case, the Agency may lift the Provisional Suspension.

(g) If the application to have a Provisional Suspension not imposed/lifted is not granted, a further application may not be made to lift the Provisional Suspension unless: (1) it is based on new and material evidence that the Responsible Person or other Covered Person was not aware of and could not reasonably have been aware of at the time he or she made the original application; or (2) there has been some other significant and material change in circumstances since the original application was decided. If the Responsible Person or other Covered Person makes a further application that does not meet either of these requirements, costs may be awarded against him or her.

(h) Voluntary Provisional Suspension.

(1) In all cases where a Responsible Person/Covered Person has been notified of or charged with a Controlled Medication Rule Violation, but no Provisional Suspension has been imposed on him or her or on the Covered Horse, that person may (on his or her own behalf and, if the Responsible Person, on behalf of the Covered Horse where it might be subject to a period of Ineligibility), voluntarily accept a Provisional Suspension at any

time by written notice to the Agency. A copy of the voluntary Provisional Suspension shall promptly be provided to each Interested Party.

(2) A Provisional Suspension that is voluntarily accepted will have effect (in the same manner as if the Provisional Suspension had been imposed under Rule 3347(a)) from the date that written notice of its acceptance is received by the Agency.

(i) No admission will be inferred, or other adverse inference drawn, from the decision of a Covered Person: (1) not to make an application to lift a Provisional Suspension; or (2) to accept a voluntary Provisional Suspension.

(j) If a Provisional Suspension is imposed or voluntarily accepted, and that Provisional Suspension is respected, then the Responsible Person/Covered Person and Covered Horse in question shall receive a credit for such period of Provisional Suspension against any period of Ineligibility that may ultimately be imposed. If the Responsible Person/Covered Person or Covered Horse does not respect a Provisional Suspension, the Responsible Person/Covered Person or Covered Horse shall receive no credit for any period of Provisional Suspension served. If a period of Ineligibility is served pursuant to a decision that is subsequently subject to review, the Responsible Person/Covered Person or Covered Horse shall receive a credit for such period of Ineligibility served against any period of Ineligibility that may ultimately be imposed on review.

(k) Notwithstanding any other provision in this Rule 3347 or elsewhere in the Protocol, any Provisional Suspension imposed on a Covered Horse will be automatically lifted (without the need for any hearing) if it has been in place for a period equal to the period of Ineligibility specified in the Protocol or Prohibited List.

Rule 3348. Charge Letter

If, after receipt of the Covered Person's explanation, or expiry of the deadline to provide such explanation, the Agency remains satisfied that the Covered Person has committed a Controlled Medication Rule Violation(s), the Agency shall promptly charge the Covered Person with the asserted Controlled Medication Rule Violation(s). In this letter of charge (Charge Letter), which will be copied to each Interested Party, the Agency shall:

(a) set out the Controlled Medication Rule Violation(s) that the Covered Person is charged with having committed;

(b) provide a summary of the relevant facts upon which the charge is based, enclosing a copy of the A Sample Laboratory Documentation Package and (if applicable and if requested) the B Sample Laboratory Documentation Package;

(c) specify the Consequences that will apply if the charge is upheld;

(d) grant a deadline of not more than 7 days from receipt of the Charge Letter (unless otherwise agreed by the Agency) for the Covered Person to either:

(1) admit the Controlled Medication Rule Violation(s) charged and:

(i) accept the Consequences proposed by the Agency, in which case the Agency will issue a decision under Rule 3349,

(ii) seek to agree mitigated Consequences with the Agency pursuant to Rule 3349 failing which the Consequences may still be disputed at a hearing; or

(iii) dispute or seek to mitigate the proposed Consequences at a hearing in accordance with Rule 3361 and the Arbitration Procedures; or

(2) deny the Controlled Medication Rule Violation charged and dispute the proposed Consequences at a hearing in accordance with Rule 3361 and Arbitration Procedures;

(e) indicate that if the Covered Person does not challenge the Agency's assertion of a Controlled Medication Rule Violation or the proposed Consequences within the prescribed deadline, the Covered Person shall be deemed to have waived his or her right to a hearing, admitted the Controlled Medication Rule Violation(s) charged, and accepted the Consequences specified by the Agency in the Charge Letter (without any mitigation of those Consequences);

(f) give the opportunity to provide Substantial Assistance in accordance with Rule 3326(a); and

(g) provide all relevant details relating to any Provisional Suspensions (including, if applicable, the possibility to accept a voluntary Provisional Suspension) in accordance with Rule 3347.

Rule 3349. Case Resolution Without a Hearing

(a) At any time prior to a final decision under the Arbitration Procedures: (1) the Agency may withdraw a Charge Letter for good cause, in which case any Provisional Suspension will be automatically lifted and (absent the emergence of new information) no further steps will be taken in relation to the violations alleged in the Charge Letter; or (2) the Covered Person may agree to admit the Controlled Medication Rule Violation(s) charged (or any other violation of the Protocol) and accede to specified Consequences consistent with the Protocol. In any such case, an adjudication under the Arbitration Procedures will not be required.

(b) In the event that the Covered Person admits the Controlled Medication Rule Violation(s) charged and accedes to Consequences specified by the Agency (or is deemed to have done so in accordance with Rule 3348(a)(5)), the Agency will (1) promptly issue a final decision confirming the commission of the Controlled Medication Rule Violation(s) and setting out the factual basis for the decision and all of the Consequences to be imposed (including a brief summary of the reasons for any period of Ineligibility imposed, unless doing so could compromise an ongoing investigation or proceeding), and (2) send notice of the decision to each Interested Party. The Agency will also Publicly Disclose the decision (or a summary thereof, at the discretion of the Agency) in accordance with Rule 3620.

(c) In the event that the Agency withdraws the Charge Letter, it will (1) promptly issue a summary decision confirming the withdrawal of the Charge Letter, (2) send notice of the decision to the Covered Person concerned, with a copy to each Interested Party, and (3) Publicly Disclose the decision (or a summary thereof, at the discretion of the Agency) in accordance with Rule 3620.

Rule 3350. Notification Requirements

(a) Notification of Controlled Medication Rule Violations will take place as set out in Rule 3345 and Rule 3348. If at any point after an ECM Notice has been provided the Agency decides not to move forward with the charge, it will notify the Covered Person(s) concerned and each Interested Party of that decision.

(b) Notification to a Covered Person by the Agency, for all purposes of the Protocol, may be accomplished either through actual or constructive notice. Actual notice may be accomplished by any means. Constructive notice shall be deemed to have been given when the information in question is 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 or text message to the Covered Person's most recent email address or mobile telephone number on file with the Authority.

3360. Hearings and Review of Final Decisions

Rule 3361. Procedure Before the Internal Adjudication Panel

Where a Covered Person is alleged to have committed a Controlled Medication Rule Violation, a violation of Rule 3329, or any violation of Rule 3510, the Covered Person shall be entitled to request a hearing before the Internal Adjudication Panel in accordance with the Arbitration Procedures. However, the Internal Adjudication Panel may decide, in its sole discretion, to determine the matter based solely on the written submissions without a hearing if the Internal Adjudication Panel considers itself sufficiently well-informed to render a decision on the written submissions alone. A copy of the final decision of the Internal Adjudication Panel shall be sent to the Agency and the Covered Person(s) concerned. Where the Agency considers it necessary or appropriate to do so, a copy of the decision may be sent to any Interested Party. The decision (or a summary thereof, at the discretion of the Agency) shall be Publicly Disclosed as provided in Rule 3620. The Internal Adjudication Panel may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Internal Adjudication Panel.

Rule 3362. Expedited Hearing

In Controlled Medication Rule Violation cases where the Covered Horse or Covered Person in question is not Provisionally Suspended and is likely to participate in a Covered Horserace within 45 days, the Agency may (if it sees fit) address the case on an expedited basis and shorten any deadlines in the Protocol or Arbitration Procedures proportionately to ensure resolution of the matter prior to the Covered Horserace.

Rule 3363. Finality

Subject to Rule 3364, decisions rendered by the Internal Adjudication Panel under the Protocol shall be final and binding.

Rule 3364. Review of Final Decisions

Any final decision by the Agency or the Internal Adjudication Panel is subject to review in accordance with section 3058 of the Act. Any final decision under review shall remain in effect pending resolution of the review unless ordered otherwise.

3500. Other Violations

Rule 3510. Other Violations Under the Protocol

Where a Covered Person:

(a) engages in disruptive or offensive conduct towards a Doping Control official or other Person involved in Doping Control that does not rise to the level of Tampering;

(b) refuses or fails to cooperate promptly and completely with the Authority or the Agency in the exercise of their respective powers under the Act and the Protocol and related rules, including any refusal or failure to comply with Rule 3040(a)(2);

(c) commits a Whereabouts Failure; or

(d) refuses or fails without compelling justification to comply with any other provision of the Protocol (where such refusal or failure does not constitute an Anti-Doping Rule Violation);

the Covered Person will not be deemed to have committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation. However, disciplinary proceedings may be brought against him or her before the Internal Adjudication Panel in accordance with the Arbitration Procedures or resolved without a hearing applying the rules of proof set out in Rule 3120 and following the procedures set out in section 3360 (in each case, mutatis mutandis, *i.e.,* amended as required to reflect the different context). The Agency will send the Covered Person at issue a notice of the alleged violation, setting out a summary of the relevant facts upon which the charge is based, and giving the Covered Person the opportunity to provide an explanation within a short deadline. If the Internal Adjudication Panel finds the violation alleged to be proven, or if the Covered Person admits the violation alleged and does not request a hearing to determine the consequences, the Internal Adjudication Panel or the Agency (as applicable) may impose sanctions on Covered Persons as set out in Rule 3520.

Rule 3520. Sanctions for Other Violations Under the Protocol

(a) For a violation of Rule 3510(a) (disruptive or offensive conduct), the Covered Person shall be subject to, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, 30 days of Ineligibility, depending on the seriousness of the violation. A fine of up to $5,000 may also be imposed.

(b) For a violation of Rule 3510(b) (refusal or failure to cooperate), the Covered Person shall be subject to, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, a period of Ineligibility of up to 2 years, depending on the seriousness of the violation. A fine of up to $15,000 may also be imposed. A failure to comply with Rule 3040(b)(7) will be considered a particularly serious violation that will ordinarily warrant the imposition of the maximum sanction.

(c) For a violation of Rule 3510(c) (Whereabouts Failures), the Covered Person shall not be subject to any penalty for the first Whereabouts Failure, but shall be subject to a fine of $250 for the second Whereabouts Failure, and a fine of $500 for the third Whereabouts Failure. For any subsequent Whereabouts Failures, the fine will increase by $500 each time (*i.e.,* $1,000 for the fourth failure, $1,500 for the fifth failure, etc.).

(d) For a first violation of Rule 3510(d) (refusal or failure to comply with any other provision of the Protocol), the Covered Person shall be subject to, at a minimum, a reprimand and no period of Ineligibility, and, at a maximum, 30 days of Ineligibility, as well as a fine of up to $2,500, depending on the seriousness of the violation.

(e) For any second or subsequent Rule 3510 violation, the maximum potential Ineligibility and potential fine will be double what the maximum potential Ineligibility and potential fine was for the previous violation.

(f) Where a violation of Rule 3510 is alleged and the Covered Person represents a threat to the health, safety, or welfare of horses or the integrity of the sport of horseracing, the Agency may impose a Provisional Suspension on the Covered Person concerned pending resolution of the charge. The Covered Person may challenge the Provisional Suspension in accordance with Rule 3347 (which shall apply mutatis mutandis, *i.e.,* amended as required to reflect the different context).

3600. Confidentiality and Reporting

Rule 3610. Notice of Violations and Confidentiality

(a) Notice.

(1) Notice of Anti-Doping Rule Violation or Controlled Medication Rule Violations shall be sent to the Covered Persons concerned, with a copy to each Interested Party, as set out in Rules 3245/3248 and 3345/3348.

(2) Notice of other violations shall be sent to the Covered Persons concerned. The Agency may send a copy to any Interested Party where it considers it necessary or appropriate to do so in the circumstances.

(3) State Racing Commissions shall only be entitled to receive notice of violations of the Protocol as Interested

Parties if they first enter into an agreement with the Agency incorporating confidentiality provisions required by the Agency pursuant to the Act or the Protocol. The Agency may, in its sole discretion, delay notice to the State Racing Commission for case- or investigation-related reasons.

(b) Confidentiality and public reporting.

(1) Subject to the other provisions of this paragraph (b), the Agency will use its reasonable endeavors to ensure that Persons under its control do not publicly identify Covered Horses or Covered Persons who are alleged to have committed a violation under the Protocol, unless and until (i) in presence cases, the B Sample confirms the results of the A Sample analysis, or the B Sample analysis is waived, (ii) a Provisional Suspension has been imposed or voluntarily accepted, (iii) a charge has been brought, or (iv) a violation has been admitted, whichever is earlier.

(2) In such circumstances, subject to paragraph (3) below, the Agency shall publicly report:

(i) the identity of any Covered Person who is the subject of the alleged violation;

(ii) the identity of any relevant Covered Horse(s); and

(iii) the rule violated and, where appropriate, the basis of the asserted violation.

(3) The Agency shall not be required to publicly report a matter under this paragraph (b) if it would risk compromising an ongoing investigation or proceeding. When the Agency determines that an ongoing investigation or proceeding will no longer be compromised by public reporting, the Agency shall at such time make any public reporting required under this Rule.

(4) The mandatory public reporting under Rule 3610(b) shall not be required where the Covered Person who is alleged to have committed a violation is a Minor. Any optional public reporting in a case involving a Minor shall be proportionate to the facts and circumstances of the case.

(5) If at any time information pertaining to an alleged violation is publicly reported by a Person not affiliated with the Authority or the Agency, the Agency may respond to such public comment as it considers necessary.

(6) The Agency may publicly report any relevant information at any time, including prior to delivery of notice of a violation, if the Agency determines that such disclosure:

(i) concerns a violation or circumstance that poses a serious and imminent risk of harm to any Covered Person(s), Covered Horse(s), State Racing Commission(s), Racetrack(s), Race Organizer(s), Training Facilities, or the public; or

(ii) is otherwise in the best interest of horseracing conducted at Covered Horseraces.

(7) The Agency may at any time disclose to other Persons such information as the Agency considers necessary or appropriate to facilitate administration or enforcement of the Protocol (including Interested Parties and other Persons with a need to know), provided that each Person provides assurance satisfactory to the Agency that the organization will maintain all such information in confidence.

(8) Interested Parties and other Persons may not publicly report any information about an alleged violation unless the information has been publicly reported by the Agency or the Covered Person(s) concerned, or the Agency gives written authorization for him or her to publicly report the information.

Rule 3620. Public Disclosure

(a) The Agency shall Publicly Disclose the resolution of an alleged violation of the Protocol no later than 20 calendar days after:

(1) the final decision;

(2) a resolution between the Agency and the Covered Person; or

(3) the withdrawal of a charge or a final decision finding of no violation.

(b) Public Disclosure shall include:

(1) the name of the Covered Person who committed the violation(s) and any Covered Horse(s) implicated by the violation;

(2) the Rule(s) violated;

(3) the Prohibited Substance(s) or Prohibited Method(s) involved, if any;

(4) the Consequences imposed;

(5) any final decision or a summary thereof, unless publishing that decision could compromise an ongoing investigation or proceeding, and excluding decisions made by the Agency with respect to Atypical Findings pursuant to Appendix 1; and

(6) any review rights available in respect of the decision.

(c) The mandatory Public Disclosure required by this 3620 shall not be required where the Covered Person who has been found to have committed a violation is a Minor. Any optional Public Disclosure in a case involving a Minor shall be proportionate to the facts and circumstances of the case.

(d) Publication shall be accomplished by, at a minimum, placing the required information on the Agency's website.

Rule 3630. General Reporting

The Agency may publish general statistical reports of its Doping Control and Medication Control activities and may report as necessary on its activities to the U.S. Congress, the Commission, the Authority, the State Racing Commissions, and other Federal or State governmental bodies or agencies having jurisdiction over the sport of horseracing in the United States. The Agency may also publish reports showing the names of any Covered Horses Tested and the date of each Sample collection.

Rule 3640. Data Privacy

The Agency may collect, store, process, or disclose personal information relating to Covered Persons, Covered Horses, or other Persons and horses where necessary and appropriate to discharge its responsibilities under the Protocol, but shall take appropriate steps to maintain that information and its confidentiality in compliance with applicable law.

3700. Implementation of Decisions

Rule 3710. Application and Recognition of Decisions

(a) Any final decision issued pursuant to the Protocol that a violation of the Protocol has taken place and imposing Consequences or other sanctions for that violation shall be automatically and immediately recognized, respected, enforced and given full force and effect by the Authority, Racetracks, Race Organizers, Training Facilities, all Covered Persons, and all other relevant Persons within their respective spheres of authority.

(b) Where a third party with its own jurisdiction over Covered Persons or Covered Horses imposes consequences on them for violation of anti-doping or controlled medication rules that are consistent with the Protocol or the World Anti-Doping Code, that decision, upon review and acceptance by the Authority and the Agency, shall be immediately recognized, respected, enforced and given full force and effect by the Agency, the Authority, Racetracks, Race Organizers, all Covered Persons, and all other relevant Persons within their respective spheres of authority.

3800. Education

Rule 3810. Education Programs

The Agency shall plan, implement, evaluate, and monitor education programs for responsible medication use and doping-free horseracing.

Rule Series 3000 Appendix 1: Atypical Findings Policy

Overview

1. Atypical Findings occur when the Laboratory provides the results of its analysis of a Sample to the Agency and more investigation or review is needed to determine whether or not it should be treated as an Adverse Analytical Finding. This Atypical Findings Policy (Atypical Findings Policy) sets out the process by which the Agency will decide whether or not Atypical Findings will be pursued as Adverse Analytical Findings.

Prohibited Substances To Be Treated as Atypical Findings

2. If detected in the Sample of a Covered Horse, the following Prohibited Substances shall be investigated or reviewed as Atypical Findings:

(a) Specified Substances;

(b) endogenous substances;

(c) ractopamine; and

(d) zilpaterol.

3. The Laboratory may also report other Atypical Findings in relation to substances that are not specifically listed in the Prohibited List or Technical Document-Prohibited Substances.

Decisions Regarding Atypical Findings

4. The Agency is responsible for issuing a decision regarding whether or not an Atypical Finding will be pursued as an Adverse Analytical Finding.

5. Subject to the notification requirements set out below, the deliberations of the Agency shall be confidential.

Preliminary Steps

6. Initial review.

The Agency will first conduct a review to determine whether there is any apparent departure from any Standards or any provisions of the Protocol that caused the Atypical Finding. If that review does not reveal any departure that caused the Atypical Finding, the Agency will conduct the required investigation in accordance with this Atypical Findings Policy. The precise nature of the investigation will depend on basis for the Atypical Finding, including the Prohibited Substance(s) associated with the Atypical Finding (if applicable), and the level of cooperation of the Responsible Person.

7. Notification.

The Agency will promptly inform the Responsible Person and Interested Parties in writing of the Atypical Finding and any relevant information, such as the Covered Horserace to which the Atypical Finding relates, and the Responsible Person will have the opportunity to provide any information that he or she believes might assist the Agency in deciding whether or not to pursue the Atypical Finding as an Adverse Analytical Finding, as set forth in the criteria below. Such information must be provided to the Agency by the deadlines set by the Agency in order for it to be considered by the Agency.

8. Additional information.

The Agency may request such additional information or explanations from the Responsible Person as it considers necessary to evaluate the Atypical Finding, and the Responsible Person must comply fully and promptly with any such requests.

Criteria

In deciding whether or not an Atypical Finding should be pursued as an Adverse Analytical Finding, the Agency will consider the following criteria:

9. Proving source of the Prohibited Substance(s) as a precondition.

(a) The Responsible Person has the burden of proving how the Prohibited Substance(s) entered the body of the Covered Horse. If the Responsible Person is unable to discharge that burden, the Atypical Finding must be pursued as an Adverse Analytical Finding. If the Responsible Person proves the source, the Agency will determine whether or not the Analytical Finding should be pursued as an Adverse Analytical Finding.

(b) The Agency will take a number of factors into account when considering whether or not the source of the Atypical Finding has been established including, but not limited to:

(i) if there were Atypical Findings for the same Prohibited Substance(s) arising from other Samples collected at the relevant Covered Horserace;

(ii) if there were Atypical Findings for the same Prohibited Substance(s) arising from other Samples collected at previous Covered Horseraces held at the same Racetrack or in the same region;

(iii) if Samples taken from feed or bedding at the relevant Covered Horserace (if such samples are available) test positive for the Prohibited Substance(s) in question;

(iv) if there were other (non-Atypical Finding) Prohibited Substance(s) in the Sample; and

(v) the concentration level of the particular Prohibited Substance(s) in the Sample.

(c) In addition, the Agency may, in accordance with Rules 3246 and 3346 of the Protocol, request the B Sample analysis.

(d) If the Atypical Finding concerns a Prohibited Substance(s) that is an endogenous substance, the Agency will request that the Responsible Person provide any veterinary information that would assist in establishing if the result is due to a physiological or pathological condition, and such information shall be taken into account by the Agency.

(e) When trying to establish the source of the Prohibited Substance(s) in question, the Agency may consult, as necessary, with one or more experts to obtain further information on the Prohibited Substance(s) in order to assess whether or not: (i) the explanations provided by the Responsible Person (if any) are plausible; or (ii) the presence of the Prohibited Substance(s) in the Sample is likely to be due to contamination.

(f) The Agency will consider any measures the Responsible Person has in place to prevent Prohibited Substances entering the body of his or her Covered Horse(s), including:

(i) whether or not the Responsible Person keeps up-to-date treatment records;

(ii) whether or not the Responsible Person keeps a record of the feed or supplements given to his or her Covered Horses, and whether samples of such feed or supplements have been stored for potential analysis;

(iii) the security measures put in place by the Responsible Person at his or her stables and when travelling to or attending Covered Horseraces; and

(iv) other measures taken by the Responsible Person to prevent Prohibited Substances inadvertently entering the body of his or her Covered Horses.

10. Other factors.

The Agency may also have regard to other factors that it considers necessary or relevant, including, but not limited to:

(a) the security measures in place at the relevant Covered Horserace;

(b) the report(s) of the Veterinarians or stewards at the relevant Covered Horserace;

(c) the prevalence of the use of the Prohibited Substance(s); and

(d) whether or not the Responsible Person has any prior Anti-Doping Rule Violation(s) or Controlled Medication Rule Violation(s) (excluding any violations where the Responsible Person was found to bear No Fault or Negligence).

Conclusion of the Investigation and Notification

11. Following the Agency's investigation of the Atypical Finding in accordance with the criteria above, the

Agency shall decide whether or not the Atypical Finding should be pursued as an Adverse Analytical Finding. The Agency shall issue a written decision, with a short summary of the basis for that decision. The decision of the Agency is final and is not subject to review. The Agency will send a copy of its decision to the Responsible Person.

12. If the Agency determines that the Atypical Finding should not be pursued as an Adverse Analytical Finding, no further action will be taken, and no case will be opened against the Responsible Person.

13. If the Agency determines that the Atypical Finding should be pursued as an Adverse Analytical Finding, the Agency will follow the notification procedure set out in Rules 3250 and 3350 and will refer the matter for adjudication in accordance with the Arbitration Procedures (unless the matter is resolved by agreement without a hearing as permitted under the Protocol). The Agency may rely on any information submitted or obtained when investigating the Atypical Finding in the subsequent Adverse Analytical Finding case.

Publication of Atypical Findings

14. At the end of each year, the Agency may publish a report setting out the following information, on an anonymised basis:

(a) how many Atypical Findings were reported by Laboratories that year;

(b) how many Atypical Findings were pursued as Adverse Analytical Findings, and the Prohibited Substances in question;

(c) how many Atypical Findings were not pursued as Adverse Analytical Findings, and the Prohibited Substances in question; and

(d) how many Atypical Findings remain under investigation.

Public Comment

15. Unless there are compelling reasons (as determined by the Agency), no Person may make any public comment on the specific details of an Atypical Finding while the investigation is ongoing. If such a disclosure is made by a Person not affiliated with the Authority or the Agency, the Authority or the Agency may respond to such public comment as it considers necessary.

16. If an Atypical Finding is not pursued as an Adverse Analytical Finding, no Person may make any public comment on the details of that Atypical Finding without the prior consent of the Responsible Person. If such a disclosure is made by a Person not affiliated with the Authority or the Agency, the Authority or the Agency may respond to such public comment as it considers necessary.

4000. Prohibited List

4010. Purpose

In accordance with Rule 3111, the Prohibited List identifies substances and methods that are prohibited at all times (Banned Substances and Banned Methods) and those that are prohibited for Use or Administration in relation to a Covered Horse during the Race Period and prohibited to be present in a Post-Race Sample or Post-Work Sample, except as otherwise specified in the Prohibited List (Controlled Medication Substances and Controlled Medication Methods). In accordance with the definition of ''Race Period'' (see Rule 1020), the Prohibited List may specify that, for certain specified Controlled Medication Substances and Controlled Medication Methods, the Race Period shall be shorter or longer in duration. Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (*e.g.,* anabolic steroids) or by specific reference to a particular substance or method. The Prohibited List is supplemented by the ''Technical Document—Prohibited Substances,'' which provides guidance on the Prohibited Substances that fall into the general categories listed in the Prohibited List and on the Screening Limits, Thresholds, or Detection Times for those Prohibited Substances (as applicable), and also designates certain Prohibited Substances as Specified Substances, which are those that pose a higher risk of being the result of contamination and, therefore, are subject to more flexible sanctions. Certain Prohibited Substances might also first be reported as Atypical Findings requiring further investigation before being declared as Adverse Analytical Findings, in accordance with the Atypical Findings Policy set out as Appendix 1 to the Protocol. The Prohibited List also sets out the periods of Ineligibility applicable to Covered Horses for Anti-Doping Rule Violations and Controlled Medication Rule Violations (see Rule 4300).

4100. Banned Substances and Banned Methods

4110. Banned Substances

Rule 4111. S0 Non-Approved Substances

Any pharmacological substance that (i) is not addressed by Rules 4112 through 4117, (ii) has no current approval by any governmental regulatory health authority for veterinary or human use, and (iii) is not universally recognized by veterinary regulatory authorities as a valid veterinary use, is prohibited at all times. For the avoidance of doubt, compounded products compliant with the Animal Medicinal Drug Use Clarification Act (AMDUCA) and the FDA Guidance for Industry (GFI) #256 (also known as Compounding Animal Drugs from Bulk Drug Substances) are not prohibited under this section S0.

Rule 4112. S1 Anabolic Agents

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

(a) anabolic androgenic steroids when administered exogenously;

(b) other anabolic agents, including, but not limited to:

(1) Selective Androgen Receptor Modulators (SARMs);

(2) Zeranol;

(3) Zilpaterol; and

(4) Ractopamine.

Rule 4113. 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 at all times:

(a) Erythropoietins (EPO) and agents affecting erythropoiesis, including, but not limited to:

(1) erythropoietin-receptor agonists;

(2) Hypoxia-Inducible Factor (HIF) activating agents;

(3) GATA (Erythroid Transcription Factor) inhibitors;

(4) Transforming Growth Factor-beta (TGF-β) signaling inhibitors; and

(5) innate repair receptor agonists.

(b) Peptide Hormones and their releasing factors, including, but not limited to:

(1) Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their releasing factors in stallions, ridglings, and geldings;

(2) corticotrophins and their releasing factors (excluding ACTH if administered outside the Race Period);

(3) Growth Hormone (GH) and its analogues and fragments; and

(4) Growth Hormone (GH) releasing factors.

(c) Growth factors and growth factor modulators affecting muscle, tendon, or ligament protein synthesis/degradation, vascularization, energy utilization, regenerative capacity, or fiber type switching.

Rule 4114. S3 Beta-2 Agonists

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times: all selective and non-selective beta-2 agonists, including all optical isomers. Notwithstanding the above, the following are not prohibited under this section S3:

(a) inhaled beta-2 agonists (*e.g.,* albuterol, salbutamol) when prescribed by a Veterinarian (in the context of a valid veterinarian-patient-client relationship) as a bronchodilator; and

(b) clenbuterol when prescribed by a Veterinarian (in the context of a valid veterinarian-patient-client relationship) for a duration not to exceed 30 days in a 6-month period and provided that, following administration of clenbuterol, the Covered Horse shall be placed on the Veterinarians' List and shall not be eligible to participate in any Timed and Reported Workout or Covered Horserace until a urine and a blood Sample have been collected from it by or on behalf of the Agency, and analysis by a Laboratory of those Samples does not detect the presence of clenbuterol or its Metabolites or Markers.

Rule 4115. S4 Hormone and Metabolic Modulators

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

(a) aromatase inhibitors;

(b) anti-estrogenic substances, anti-estrogens, and selective estrogen receptor modulators (SERMS);

(c) agents preventing activin receptor IIB activation, including, but not limited to, myostatin inhibitors;

(d) metabolic modulators, including, but not limited to:

(1) insulins and insulin-mimetics;

(2) meldonium; and

(3) trimetazidine; and

(e) thyroid hormone and thyroid hormone modulators.

Rule 4116. S5 Diuretics and Masking Agents

(a) Diuretics and masking agents, and other substances with a similar chemical structure or similar biological effect(s), are prohibited at all times.

(b) Notwithstanding the above, the following are not prohibited under this section S5:

(1) drospirenone, pamabrom, and topical ophthalmic administration of carbonic anhydrase inhibitors (*e.g.,* dorzolamide, brinzolamide);

(2) trichlormethiazide for treatment of edema;

(3) plasma expanders for life-saving procedures; and

(4) furosemide (also known as Lasix/Salix), subject to the limitations set out in Rule 4212(d).

Rule 4117. S6 Miscellaneous Substances

The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited at all times:

(a) bisphosphonates (except that bisphosphonates may be administered for the purpose of diagnostic imaging, *i.e.,* gamma scintigraphy);

(b) toxins (*e.g.,* botulinum toxin, botox);

(c) venoms of any species, their synthetic analogs, or derivatives thereof;

(d) altrenogest in stallions, ridglings, or geldings;

(e) pitcher plant extract (Sarapin); and

(f) perfluorocarbons.

4120. Banned Methods

Rule 4121. M1 Manipulation of Blood and Blood Components

The following are prohibited at all times:

(a) 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.

(b) 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.

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

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

(e) Notwithstanding the above, manipulation of blood or blood components is not prohibited under this section M1:

(1) procedures performed for life-saving purposes; and

(2) use of veterinary regenerative therapies (*i.e.,* autologous conditioned serum or platelet-rich plasma) for the treatment of musculoskeletal injury or disease.

Rule 4122. M2 Chemical Castration or Immunocastration

In case of chemical castration or immunocastration, the Covered Horse shall remain designated as an intact male. Designating a Covered Horse that has had chemical castration or immunocastration as a gelding constitutes Use of a Prohibited Method.

Rule 4123. M3 Gene and Cell Doping

The following, which have the potential to enhance performance or modify the heritable genome, are prohibited at all times:

(a) the use of nucleic acids or nucleic acid analogues that might alter genome sequences or alter gene expression by any mechanism. This includes, but is not limited to, gene editing, gene silencing, and gene transfer technologies;

(b) the use of normal or genetically modified cells; and

(c) modification of the heritable genome.

4200. Controlled Medication Substances and Controlled Medication Methods

4210. Controlled Medication Substances

Rule 4211. S7 Controlled Medication Substances

(a) Subject to Rule 4212, only feed, hay, and water are permitted during the Race Period. Accordingly, subject to Rule 4212, any substance administered during the Race Period or present in a Post-Race Sample (including any metabolite(s), artifact(s), and isomer(s) of such substance(s)) that does not otherwise qualify as a Banned Substance shall constitute a prohibited Controlled Medication Substance.

(b) The following Controlled Medication Substances are prohibited from presence in a Post-Work Sample:

(1) analgesics;

(2) Nonsteroidal Anti-Inflammatory Drugs (NSAIDs);

(3) local anesthetics; and

(4) corticosteroids.

(c) S7 Controlled Medication Substances exclude those substances that fall under section S0, which are Banned Substances.

Rule 4212. Exceptions to Rule 4211

(a) Medications administered or authorized by a Regulatory Veterinarian or Test Barn Veterinarian to provide medical care to a Covered Horse as a result of an injury sustained, or other adverse health event, during the Race Period are not prohibited.

(b) The following may be administered up to 24 hours prior to Post-Time:

(1) orally administered vitamins;

(2) licensed vaccines against infectious agents;

(3) anti-ulcer medications (*e.g.,* Cimetidine, Omeprazole, and Ranitidine);

(4) unsupplemented isotonic electrolyte solutions by oral or intravenous administration;

(5) altrenogest in female horses;

(6) antimicrobials (antibiotics) and other anti-infective agents, excluding procaine penicillin or other antimicrobial/anti-infective agents containing or metabolizing to Prohibited Substances; and

(7) antiparasitic/anthelmintics approved and registered for use in horses, excluding levamisole or other antiparasitic/anthelmintics metabolizing to or containing other Prohibited Substances.

(c) Unsupplemented isotonic electrolyte solutions may be consumed by the horse's free choice at any time (but may not be administered except as provided in paragraph (b) above).

(d) Furosemide (also known as Lasix or Salix):

(1) is permitted during Timed and Reported Workouts and Vets' List Workouts; and

(2) may be administered during the Race Period in accordance with specific provisions of the Act and any guidance or exceptions approved by the Authority, but shall not be administered within the 4 hours prior to Post-Time.

(e) The Use or Administration of supplements or feed additives during the Race Period shall not be prohibited if the Responsible Person or Covered Person establishes, or the Agency expressly accepts, that such substances are not 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:

(1) the blood system;
(2) the urinary system;
(3) the cardiovascular system;
(4) the digestive system;
(5) the endocrine system;
(6) the immune system;
(7) the musculoskeletal system;
(8) the nervous system;
(9) the reproductive system; or
(10) the respiratory system.

4220. Controlled Medication Method(s)

In addition to any prohibited practices set forth in the Rule 2000 Series (Racetrack Safety Program):

Rule 4221. M4 Alkalinization or Use/Administration of an Alkalinizing Agent

Alkalinization or Use/Administration of an alkalinizing agent is prohibited on Race Day. A threshold concentration of total carbon dioxide (TCO2) in the blood in excess of 37 mmol constitutes prima facie evidence of alkalinization or Use/Administration of an alkalinizing agent.

Rule 4222. M5 Intra-Articular Injections

Intra-articular injections are prohibited on Race Day; within 14 days prior to Post-Time; and within 7 days prior to any Timed and Reported Workout.

Rule 4223. M6 Nasogastric Tube

The use of a nasogastric tube for any purpose is prohibited within 24 hours prior to Post-Time.

Rule 4224. M7 Intra-Articular Injections of Polyacrylamide Hydrogels

Intra-articular injections of polyacrylamide hydrogels are prohibited within 180 days prior to Post-Time.

Rule 4225. Modification of Race Period

The start of the ''Race Period'' shall be modified for each of the Controlled Medication Methods above (*i.e.,* each of M4–M7) based on the restricted administration time period specified for such method (*e.g.,* the Race Period for M7 shall start 180 days prior to Post-Time).

4300. Ineligibility Periods for Covered Horse

4310. Violations Involving Prohibited Substances

The period of Ineligibility of a Covered Horse resulting from a violation involving a Prohibited Substance shall be as set forth in Table 1 below:

TABLE 1

Violation	Ineligibility period
S0 BANNED Substances-non-approved substances	Up to 14 months.
S1 BANNED Substances-anabolic agents	14 months.
S2 BANNED Substances-peptide hormones	6 months
S3 BANNED Substances-beta-2 agonists	14 months.
S4 BANNED Substances-hormone and metabolic modulators	3 months.
S5 BANNED Substances-diuretics and masking agents	0 months.
S6 BANNED Substances-miscellaneous substances:	
(1) Bisphosphonates	Life.
(2) All other S6 miscellaneous substances	0 months.
S7 CONTROLLED Medication Substances	0 months. The Covered Horse may be placed on the Veterinarians' List, and if so, a subsequent Vets' List Workout must be scheduled. A post-Vets' List Workout Sample may be required.

4320. Violations Involving Prohibited Methods

The period of Ineligibility of a Covered Horse resulting from a violation involving a Prohibited Method shall be as set forth in Table 2 below:

TABLE 2

Violation	Ineligibility period
M1 Manipulation of blood and blood components	6 months.
M2 Chemical castration or immunocastration	0 months.
M3 Gene and cell doping	Life.
M4 Alkalinization	0 months.
M5 Intra-articular injection	1 month.
M6 Nasogastric tube	0 months.

TABLE 2—Continued

Violation	Ineligibility period
M7 Intra-articular injection of polyacrylamide hydrogel	12 months.

4330. Other Violations Leading to a Period of Ineligibility for the Covered Horse

The period of Ineligibility of a Covered Horse resulting from a violation of Rule 3215 shall be as set forth in Table 3 below:

TABLE 3

Violation	Ineligibility Period
Evading collection of a Sample from a Covered Horse; refusing or failing without compelling justification to submit a Covered Horse to Sample collection; or refusing or failing to comply with all Sample collection procedure requirements (Rule 3215).	*Evasion:* 18 months. *Refusal or failure:* 18 months, unless it is established by the Responsible Person that fairness requires otherwise, in which case the period of Ineligibility may be reduced, depending on the specific circumstances of the case and considerations of horse welfare.

Appendix 1 to Rule Series 4000: Technical Document—Prohibited Substances

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit*
BANNED	S1		Δ-1-androstene-3, 17diol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Δ-1-androstene-3, 17dione	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Δ-1-dihydrotestosterone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		19-Norandrostenediol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		19-Norandrostenedione	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		19-Noretiocholanolone	Anabolic	Lacks FDA approval.		
BANNED	S1		1-androstenediol (5α androst-1-ene-3β, 17βdiol).	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		1-androstenedione (5αandrost-1-ene-3, 17dione).	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		1-testosterone (17βhydroxy-5α-androst-1en-3-one).	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		2-Aminoheptane (Tuaminoheptane).	Sympathomimetic/Vasoconstrictor.	Lacks FDA approval.		
BANNED	S4		2-androstenol(5α-androstane-2-en-17-ol).	Pheromone/Reproductive Hormone.	Lacks FDA approval.		
BANNED	S4		2-androstenone (5α-androst-2-en-17-one).	Pheromone/Reproductive Hormone.	Lacks FDA approval.		
BANNED	S0		3,4-methylenedioxypyrovalerone (MDVP).	Stimulant	Lacks FDA approval.		
BANNED	S4		3-androstenol (5α-androst-3-en-17-ol).	Pheromone/Reproductive Hormone.	Lacks FDA approval.		
BANNED	S4		3-androstenone (5α-androst-3-en-17-one).	Pheromone/Reproductive Hormone.	Lacks FDA approval.		
CONTROLLED	S7	A	3-Methoxytyramine	Neurotransmitter	Endogenous substance		Threshold: 4 mcg/mL total (free and conjugated) 3-methoxytyramine in urine.
BANNED	S4		4-androstenediol (androst-4-ene- 3β,17βdiol).	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S4		4-chlorometatandienone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		4-Hydroxytestosterone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S4		5-androstenedione (androst-5-ene- 3,17dione).	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		5α-Andros-2-ene-17one	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		5α-Androstane-3α, 17 α-diol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		5α-Androstane-3α, 17 β-diol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		5α-Androstane-3β, 17α-diol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		5α-Androstane-3β, 17β -diol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		5β-androstane-3 α, 17βdiol, androst-4- ene3α,17α-diol.	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		7-keto-dhea	Anabolic.			
BANNED	S1		7α-hydroxy-dhea	Anabolic.			
BANNED	S1		7β-hydroxy-dhea	Anabolic.			
BANNED	S5		Acebutolol	Antihypertensive	Generic.		
BANNED	S0		Acecarbromal	Sedative hypnotic	Lacks FDA approval.		
BANNED	S0		Acefylline	Bronchodilator	Lacks FDA approval.		

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit*
BANNED	S0		Acemetacin	NSAID	Lacks FDA approval.		
BANNED	S0		Acenocoumarol	Anticoagulant	Lacks FDA approval.		
CONTROLLED	S7	B	Acepromazine	Sedative	PromAce, Aceproject	Detection Time: 72 hrs 0.15 mg/kg single oral dose (6 horses). Detection Time: 48 hrs 0.05 mg/kg single IV dose (20 horses).	10 ng/mL as 2-(1-hydroxyethyl) promazine sulfoxide (HEPS) in urine; 0.02 ng/mL in serum or plasma.
CONTROLLED	S7	C	Acetaminophen (Paracetamol)	NSAID	Tylenol.		
BANNED	S0		Acetanilide	NSAID	Lacks FDA approval.		
BANNED	S5		Acetazolamide	Carbonic Anhydrase Inhibitor	Generic.		
BANNED	S0		Acetohexamide	Insulin secretion	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Acetophenazine	Antipsychotic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Acetophenetidin (Phenacetin)	NSAID	Lacks FDA approval.		
CONTROLLED	S7	C	Acetylcysteine	Mucolytic	Mucomyst, Parvolex.		
BANNED	S0		Acetylmorphine	Opioid Analgesic	Lacks FDA approval.		
CONTROLLED	S7	C	Acetylsalicylic acid (Aspirin)	NSAID	Generic.		
BANNED	S0		Aclidinium bromide	Bronchodilator	Tudorza Pressair; Dualkir Pressair (with formoterol).		
BANNED	S0		Adinazolam	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Adiphenine	Antispasmodic	Lacks FDA approval.		
BANNED	S0		Adrafinil	Stimulant	Lacks FDA approval.		
BANNED	S4		AICAR (5-Aminoimidazole-4-carboxamide ribonucleotide).	Metabolic modulator	Lacks FDA approval.		
CONTROLLED	S7	B	Albuterol (Salbutamol)	Bronchodilator	FDA-approved equine product Torpex no longer commercially available. Available as FDA-approved for human use via inhalation as Proair HFA, Ventolin HFA, and generic formulations.	Detection Time: 72 hours at 5 × 100 µg actuations per dose for 2 days dosed every 4 hours. *Note:* Albuterol administered by any route other than inhalation is a Banned Substance. Evidence that albuterol was administered by a route other than inhalation, regardless of the albuterol concentration in a urine sample, constitutes a Doping Violation.	SL: 0.5 ng/mL in urine.
BANNED	S0		Alclofenac	NSAID	Lacks FDA approval.		
CONTROLLED	S7	C	Alclometasone	Corticosteroid	Generic.		
BANNED	S0		Alcuronium	Muscle relaxant	Lacks FDA approval.		
BANNED	S5		Aldosterone	Diuretic	Lacks FDA approval.		
BANNED	S6		Alendronate	Bisphosphonate	Fosamax, Binosto.		
BANNED	S2		Alexamorelin	Growth Hormone	Lacks FDA approval.		
CONTROLLED	S7	A	Alfentanil	Opioid Analgesic	Alfenta. DEA Schedule II.		
CONTROLLED	S7	B	Allopurinol	Xanthine oxidase inhibitor	Lopurin, Zyloprim, Aloprim.		
BANNED	S0		Almotriptan	Selective Serotonin Receptor Agonist.	Generic.		
BANNED	S0		Alpha- pyrrolidinovalerophenone (Alpha PVP and "Bath Salts").	Stimulant/Hallucinogen	Lacks FDA approval. DEA Schedule I.		
BANNED	S2		Alpha-casozepine	Sedative	Lacks FDA approval.		
BANNED	S0		Alphadolone (Alfadolone) acetate.	Anesthetic	Lacks FDA approval.		
BANNED	S0		Alphaprodine	Opioid Analgesic	Lacks FDA approval. DEA Schedule II.		

BANNED	S0		Alphenal	Barbiturate/Anticonvulsant	Lacks FDA approval.		
BANNED	S0		Alpidem	Anxiolytic	Lacks FDA approval.		
CONTROLLED	S7	A	Alprazolam	Sedative/Anxiolytic	Xanax. DEA Schedule IV.		
BANNED	S0		Alprenolol	Antihypertensive	Generic.		
BANNED	S0		Althesin	Anesthetic	Lacks FDA approval.		
BANNED	S5		Althiazide	Diuretic	Lacks FDA approval.		
CONTROLLED—fillies and mares.	S7	C	Altrenogest	Progestogen/Estrus Suppression.	Regumate.		
BANNED-Intact males, geldings, spayed females.	S6		Altrenogest	Progestogen/Estrus Suppression.	Regumate.		
BANNED	S0		Alverine	Antispasmodic	Lacks FDA approval.		
BANNED	S0		Amantadine	Dopamine agonist	Gocovri, Osmolex ER.		
BANNED	S0		Ambenonium	Cholinesterase Inhibitor	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Ambroxol	Mucolytic	Lacks FDA approval.		
BANNED	S0		Ambucetamide	Antispasmodic	Lacks FDA approval.		
CONTROLLED	S7	C	Amcinonide	Corticosteroid	Generic.		
BANNED	S0		Amfepramone	Antidepressant	Lacks FDA approval.		
BANNED	S0		Amfetaminil	Stimulant	Lacks FDA approval.		
BANNED	S0		Amidephrine	Stimulant	Lacks FDA approval.		
BANNED	S5		Amiloride	Diuretic	Midamor.		
BANNED	S0		Amineptine	Antidepressant	Lacks FDA approval.		
CONTROLLED	S7	C	Aminocaproic acid	Anti-fibrinolytic	Amicar.		
BANNED	S4		Aminoglutethimide	Aromatase inhibitor	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Aminomethylbenzoic acid	Anti-fibrinolytic	Lacks FDA approval.		
BANNED	S0		Aminometradine	Diuretic	Lacks FDA approval.		
CONTROLLED	S7	B	Aminophylline	Bronchodilator	Generic.		
BANNED	S0		Aminopterin	Anti-neoplastic/Immunosuppressive.	Lacks FDA approval.		
BANNED	S0		Aminopyrine (Pyramidon)	Analgesic	Lacks FDA approval.		
BANNED	S0	(x)	Aminorex	Stimulant	Lacks FDA approval. DEA Schedule I.		
CONTROLLED	S7	C	Aminosalicylic acid (Salicylic acid/Salicylate).	NSAID	Paser		750 mcg/mL in urine or 6.5 mcg/mL in serum or plasma.
CONTROLLED	S7	B	Amiodarone	Antiarrhythmic	Nexterone, Pacerone.		
BANNED	S0		Amiphenazole	Respiratory Stimulant	Lacks FDA approval.		
BANNED	S5		Amisometradine	Diuretic	Lacks FDA approval.		
BANNED	S0		Amisulpride	Antipsychotic	Barhemsys.		
CONTROLLED	S7	A	Amitraz	Stimulant	Mitaban.		
CONTROLLED	S7	A	Amitriptyline	Antidepressant	Elavil.		
BANNED	S5		Amlodipine	Antihypertensive	Norvasc.		
BANNED	S0		Ammonium Chloride	Chemical neurectomy	Generic.		
BANNED	S0		Ammonium Sulphate	Chemical neurectomy	Lacks FDA approval.		
BANNED	S0		Ammonium Sulphide	Chemical neurectomy	Lacks FDA approval.		
BANNED	S0		Amobarbital	Bartiburate/Anticonvulsant	Lacks FDA approval. DEA Schedule II.		
BANNED	S0		Amoxapine	Antidepressant	Generic.		
BANNED	S0		Amperozide	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Amphetamine	Stimulant	Adzenys XR-ODT, Dyanavel XR, Evekeo. DEA Schedule II.		
BANNED	S0		Amphetaminil	Stimulant	Lacks FDA approval.		
BANNED	S0		Ampyrone	NSAID	Lacks FDA approval.		
CONTROLLED	S7	B	Amrinone (inamrinone)	Vasodilator	Amicor, Cardiotone.		
BANNED	S0		Amyl nitrite	Antihypertensive/CNS Depressant.	Lacks FDA approval.		
BANNED	S0		Amylocaine	Local anesthetic	Lacks FDA approval.		
BANNED	S2		Anamorelin	Growth Hormone	New Drug Application submitted; currently lacks FDA approval.		
BANNED	S4		Anastrozole	Anti-estrogen	Arimidex.		
BANNED	S1		Andarine	Selective Androgen Receptor Modulator (SARM).	Lacks FDA approval.		
BANNED	S1		Androst-4-ene-3α,17β diol	Anabolic	DEA Schedule III.		
BANNED	S1		Androst-4-ene-3β,17α diol	Anabolic	DEA Schedule III.		

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit*
BANNED	S1		Androst-5-ene-3α,17α diol	Anabolic	DEA Schedule III.		
BANNED	S1		Androst-5-ene-3α,17β diol	Anabolic	DEA Schedule III.		
BANNED	S1		Androst-5-ene-3β,17α diol	Anabolic	DEA Schedule III.		
BANNED	S4		Androstatrienedione (Androsta-1,4,6-triene-3,17-ddione).	Anabolic	DEA Schedule III.		
BANNED	S4		Androstenediol (androst-5-ene-3β, 17βdiol).	Anabolic	DEA Schedule III.		
BANNED	S4		Androstenedione (androst-4-ene-3, 17dione).	Anabolic	DEA Schedule III.		
BANNED	S4		Androsterone (3 βhydroxy-5 α—androstan-17-one).	Anabolic	DEA Schedule III.		
BANNED	S0		Anileridine	Opioid Analgesic	Discontinued, no FDA-approved product commercially available. DEA Schedule II.		
BANNED	S0		Anilopam	Opioid Analgesic	Lacks FDA approval.		
BANNED	S0		Anisindione	Anticoagulant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Anisotropine (Octatropine methylbromide).	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	B	Antazoline	Antihistamine (ophthalmic)	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Antipyrine	NSAID	Lacks FDA approval.		
BANNED	S0		Apazone (Azapropazone)	NSAID	Lacks FDA approval.		
BANNED	S0		Apocodeine	Dopamine agonist	Lacks FDA approval.		
BANNED	S0		Apomorphine	Opioid Analgesic	Kynmobi, Apokyn.		
BANNED	S0		Aprindine	Antiarrhythmic	Lacks FDA approval.		
BANNED	S0		Aprobarbital	Barbiturate	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Apronalide	Sedative hypnotic	Lacks FDA approval.		
BANNED	S2		ARA-290	Erythropoiesis	FDA Orphan Drug status.		
BANNED	S0		Arecoline	Stimulant	Lacks FDA approval.		
BANNED	S3		Arformoterol	Beta-2 agonist-bronchodilator	Brovana.		
BANNED	S2		Argon	Hypoxia Inducible Factor activating.			
BANNED	S4		Arimistane (Anrosta-3,5-diene-7,17-dione).	Anabolic	Lacks FDA approval.		
CONTROLLED	S7	A	Aripiprazole	Antipsychotic	Abilify.		
CONTROLLED	S7	B (x)	Arsenic	Stimulant	Environmental substance		0.3 mcg.mL total (free and conjugated) in urine.
CONTROLLED	S7	B	Articaine	Local anesthetic	Orabloc, Septocaine.		
BANNED	S2		Asialo EPO	Erythropoiesis.			
BANNED	S0		Atenolol	Antihypertensive	Tenormin.		
CONTROLLED	S7	A	Atipamezole	Alpha adrenergic antagonist	Antisedan, Revertidine.		
BANNED	S0		Atomoxetine	Stimulant	Strattera.		
CONTROLLED	S7	A	Atracurium	Muscle relaxant	Generic.		
CONTROLLED	S7	B (x)	Atropine	Anticholinergic	Atropen		60 ng/mL total (free and conjugated) in urine.
BANNED	S0		Azacylonol (γ-pipradrol)	CNS depressant	Lacks FDA approval.		
BANNED	S0		Azaperone	Sedative	Stresnil.		
BANNED	S0		Azapetine	Vasodilator	Lacks FDA approval.		
BANNED	S0		Azapropazone	NSAID	Lacks FDA approval.		
BANNED	S0		Azathioprine	Immunosuppressor	Imuran.		
BANNED	S0		Azatidine (Azatadine)	Antihistamine	Discontinued, no FDA-approved product commercially available.		
BANNED	S5		Azosemide	Diuretic	Lacks FDA approval.		
CONTROLLED	S7	B	Baclofen	Muscle relaxant	Lyvispah, Gablofen, Lioresal, Ozobax, Fleqsuvy.		
BANNED	S0		Bambuterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		

BANNED	S0		Bamifylline	Bronchodilator	Lacks FDA approval.		
BANNED	S0		Barbital (barbitone)	Sedative hypnotic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S4		Bazedoxifene	Selective Estrogen Receptor Modulator (SERM).	FDA-approved in combination with Premarin as Duavee.		
BANNED	S0		Beclamide	Anticonvulsant	Lacks FDA approval.		
CONTROLLED	S7	C	Beclomethasone	Corticosteroid	Qvar, Qnasl, Beclovent.		
BANNED	S0		Bemegride	Stimulant	Lacks FDA approval.		
BANNED	S0		Benactyzine	Anticholinergic	Lacks FDA approval.		
BANNED	S0		Benapryzine	Anticholinergic	Lacks FDA approval.		
BANNED	S0		Benazepril	Antihypertensive	Lotensin, Lotrel (with amlodipine).		
BANNED	S5		Bendroflumethiazide	Diuretic	Naturetin, Corzide.		
BANNED	S0		Benorilate	NSAID	Lacks FDA approval.		
BANNED	S0		Benoxaprofen	NSAID	Lacks FDA approval.		
CONTROLLED	S7	C	Benoxinate(Oxybucaine, Oxybuprocaine).	Local anesthetic	Altafluor Benox [with fluorescein stain].		
BANNED	S0		Benperidol	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Bentazepam	Anxioytic	Lacks FDA approval.		
CONTROLLED	S7	B	Benzocaine	Local anesthetic	Orajel, Anbesol, Lanacane.		
BANNED	S0		Benzoctamine	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Benzonatate	Antitussive (cough suppressant)	Tessalon.		
BANNED	S0		Benzphetamine	Stimulant	Generic. DEA Schedule III.		
BANNED	S0		Benzquinamide	Antipsychotic/Antiemetic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Benzthiazide	Diuretic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	A	Benztropine	Anticholinergic	Generic.		
BANNED	S0		Benzydamine	NSAID	Lacks FDA approval.		
BANNED	S0		Benzylpiperazine (BZP)	Stimulant	Lacks FDA approval.		
BANNED	S0		Bepridil	Antihypertensive	Lacks FDA approval.		
CONTROLLED	S7	C	Betamethasone	Corticosteroid	Betavet, Celestone		0.2 ng/mL in urine.
BANNED	S0		Betaprodine	Opioid Analgesic	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Betaxolol	Antihypertensive	Betoptic.		
CONTROLLED	S7	C	Bethanechol	Cholinergic	Duovoid.		
BANNED	S0		Bethanidine (Betanidine)	Antihypertensive	Discontinued, no FDA-approved product commercially available.		
BANNED	S4		Bimagrumab	Anabolic	Lacks FDA approval (Orphan drug designation withdrawn).		
BANNED	S0		Biperiden	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Biphenamine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Biprsoprolol	Antihypertensive	Ziac [with hydrochlorothiazide].		
BANNED	S0		Biriperone (Centbutindole)	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Bitolterol	Beta-2 agonist-bronchodilator	Discontinued, no FDA-approved product commercially available.		
BANNED	S1		Bolandiol (estr-4-ene3β, 17β-diol).	Anabolic	Lacks FDA approval.		
BANNED	S1		Bolasterone (7α, 17α-dimethyltestosterone).	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Boldenone	Anabolic	Equipoise. DEA Schedule III		Threshold: 0.015 mcg free and conjugated boldenone per mL in urine in male horses (other than geldings).
BANNED	S1		Boldione	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S6		Botulinum toxin	Neurotoxin	Botox, Dysport, Jeuveau.		
BANNED	S0		Brallobarbital	Barbiturate	Lacks FDA approval.		
CONTROLLED	S7	B	Bretylium	Antiarrhythmic	Generic.		
BANNED	S0		Brimonidine	Antihypertensive	Alphagan P, Qoliana, Lumify.		
CONTROLLED	S7	B	Brinzolamide	Carbonic Anhydrase Inhibitor	Simbrinza, Azopt.		
BANNED	S0		Bromantan	Psychostimulant	Lacks FDA approval.		
BANNED	S0		Bromazepam	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
CONTROLLED	S7	A	Bromfenac	NSAID	Prolensa, Bromsite.		

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit*
BANNED	S0		Bromhexine	Mucolytic	Lacks FDA approval.		
BANNED	S0		Bromisovalum	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S0		Bromocriptine	Anticholinergic	Parlodel, Cycloset.		
CONTROLLED	S7	B	Bromodiphenhydramine	Antihistamine	Ambodryl, Ambrodil.		
BANNED	S0		Bromophenethylamine	Psychedelic	Lacks FDA approval.		
BANNED	S0		Bromperidol	Antipsychotic	Lacks FDA approval.		
CONTROLLED	S7	B	Brompheniramine	Antihistamine	Dimetapp.		
BANNED	S0		Brotizolam	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S0		Bucetin	NSAID	Lacks FDA approval.		
BANNED	S0		Buclizine	Antihistamine/Anti-emetic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	C	Budesonide	Corticosteroid	Uceris, Entocort, Tarpeyo, Ortikos, Pulmicor Flexhaler, Symbicort (with formoterol), Rhinocort Allergy.		
BANNED	S0		Bufexamac	NSAID	Lacks FDA approval.		
BANNED	S0		Buflomedil	Vasodilator	Lacks FDA approval.		
BANNED	S0	(x)	Bufotenine	Hallucinogen	Lacks FDA approval. DEA Schedule I.		10 mcg/mL Total (free and conjugated) in urine.
BANNED	S5		Bumetanide	Diuretic	Bumex.		
BANNED	S0		Bunitrolol	Vasodilator	Lacks FDA approval.		
BANNED	S0		Bunolol	Anti-hypertensive	Betagan.		
BANNED	S0		Buphenine (nylidrin)	Vasodilator	Lacks FDA approval.		
CONTROLLED	S7	B	Bupivacaine	Local anesthetic	Marcaine, Sensorcaine, Exparel.		
BANNED	S0		Bupranolol	Antihypertensive	Lacks FDA approval.		
CONTROLLED	S7	A	Buprenorphine	Analgesic	Simbadol, Zorbium,Butrans, Sublocade, Belbuca, Buprenex, Zubsolv. DEA Schedule III.		
BANNED	S0		Bupropion	Antidepressant	Wellbutrin, Zyban.		
BANNED	S4		Buserelin	Gonadotropin Releasing Hormone.	Lacks FDA approval.		
CONTROLLED	S7	A	Buspirone	Anxiolytic	Generic.		
BANNED	S0		Butabarbital (Secbutobarbitone)	Barbiturate	Discontinued, no FDA-approved product commercially available. DEA Schedule III.		
BANNED	S0		Butacaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Butalbital (Talbutal)	Barbiturate	Esgic, Fioricet. DEA Schedule III.		
CONTROLLED	S7	C	Butamben (butyl aminobenzoate).	Local anesthetic	Cetacaine.		
BANNED	S0		Butanilicaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Butaperazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Butoctamide	Serotonin release	Lacks FDA approval.		
BANNED	S0		Butofilolol	Antihypertensive	Lacks FDA approval.		
CONTROLLED	S7	B	Butorphanol	Sedative	Torbugesic, Tobutrol, Stadol, Dolorex. DEA Schedule IV.	Detection Time: 72 hrs. 0.1 mg/kg single IV dose (6 horses).	1 ng/mL in hydrolyzed urine or 0.01 ng/mL plasma or serum.
BANNED	S0		Butoxycaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Cafedrine	Cardiac Stimulant	Lacks FDA approval.		
CONTROLLED	S7	B (x)	Caffeine	Stimulant	Cafcit, Migergot (with ergotamine), combined with NSAIDs in OTC formulations. Recognized by IFHA as Feed Contaminant.		50 ng/mL (free and conjugated) in urine.
BANNED	S0		Calcium dobesilate	Vasoprotective	Lacks FDA approval.		
BANNED	S1		Calusterone (*Methosarb, Riedemil, NSC–88536, U–22550*).	Anabolic	Lacks FDA approval. (*NSC–88536, U–22550*) DEA Schedule III.		
BANNED	S0		Camazepam	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		

CONTROLLED	S7	C	Camphor	Local anesthetic	Vicks VapoRub.		
BANNED	S0		Candesartan	Antihypertensive	Atacand.		
CONTROLLED	S7	B	Cannabidiol (CBD)	Analgesic/anti-inflammatory.			
BANNED	S0	(x)	Cannabinoids (natural, synthetic and other cannabimimetics).	Psychotropic	Lack FDA approval.		
BANNED	S5		Canrenone	Diuretic	Lacks FDA approval.		
BANNED	S1		Capromorelin	Anabolic	Entyce, Elura.		
CONTROLLED	S7	B	Capsaicin	Topical analgesic/irritant	Zostrix, Salonpas Hot.		
BANNED	S0		Captodiame (captodiamine)	Antihistamine	Lacks FDA approval.		
BANNED	S0		Captopril	Antihypertensive	Generic.		
BANNED	S0		Caramiphen	Anticholinergic	Lacks FDA approval.		
BANNED	S0		Carazolol	Antihypertensive	Lacks FDA approval.		
CONTROLLED	S7	B	Carbachol	Cholinergic	Miostat.		
CONTROLLED	S7	B	Carbamazepine	Anticonvulsant	Tegretol, Carbatrol, Equetro, Teril.		
BANNED	S2		Carbamylated EPO (CEPO)	Erythropoiesis.			
BANNED	S0		Carbazochrome (Adrenochrome monosemicarbazone).	Hemostatic	Lacks FDA approval.		
BANNED	S0		Carbetapentane (pentoxyverine)	Antitussive	Lacks FDA approval.		
BANNED	S0		Carbidopa	Decarboxylase Inhibitor	Lodosyn; Stalevo, Rytary, Duopa, Dhivy, Sinemet (all with levodopa).		
BANNED	S0		Carbimazole	Anti-hyperthyroidism	Lacks FDA approval.		
CONTROLLED	S7	B	Carbinoxamine	Antihistamine	Karbinal ER.		
BANNED	S0		Carbocysteine	Mucolytic	Lacks FDA approval.		
BANNED	S0		Carbomral	Sedative hypnotic	Lacks FDA approval.		
BANNED	S0		Carbuterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
BANNED	S1		Cardarine (GW–501, GW516, GSK–516).	Selective Androgen Receptor Modulator (SARM).	Lacks FDA approval.		
BANNED	S0		Carfentanil	Opioid Analgesic	Lacks FDA approval. DEA Schedule II.		
CONTROLLED	S7	B	Carisoprodol	Muscle relaxant	Soma. DEA Schedule IV.		
BANNED	S0		Carphedon	Psychostimulant	Lacks FDA approval.		
BANNED	S0		Carphenazine	Antipsychotic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Carpipramine	Antipsychotic	Lacks FDA approval.		
CONTROLLED	S7	B	Carprofen	NSAID	Rimadyl.		
BANNED	S3		Carteolol	Antihypertensive	Generic.		
CONTROLLED	S7	B	Carticaine (see Articaine)	Local anesthetic	Septocaine, Orbloc.		
BANNED	S0		Carvedilol	Antihypertensive	Coreg.		
BANNED	S0		Cathinone	Stimulant	Lacks FDA approval. DEA Schedule I.		
CONTROLLED	S7	B	Celecoxib	NSAID	Celebrex.		
BANNED	S0		Celiprolol	Anti-hypertensive	Lacks FDA approval.		
BANNED	S0		Cephaeline	Emetic, plant alkaloid	Lacks FDA approval.		
CONTROLLED	S7	C	Cetirizine	Antihistamine	Quzyttir, Zerviate, Zyrtec	Detection Time: 48 hours. 0.4 mg/kg twice daily for 5 doses. (9 horses).	3 ng/mL in serum or plasma.
BANNED	S0		Chlomethiazole	Anticonvulsant	Lacks FDA approval.		
BANNED	S0		Chloral (cloral) betaine	Sedative/Hypnotic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Chloral hydrate	Sedative	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Chloralose (AlphaChloralose)	Anxiolytic	Lacks FDA approval.		
BANNED	S0		Chlorcyclizine	Antihistamine	Lacks FDA approval.		
BANNED	S0		Chlordiazepoxide	Anxiolytic	Librium; Librax (with chlordiazepoxide hydrochloride). DEA Schedule IV.		
BANNED	S0		Chlormadinone acetate	Reproductive hormone	Lacks FDA approval.		
BANNED	S0		Chlormerodrin	Diuretic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Chlormezanone	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Chloroform	Anesthetic	Lacks FDA approval.		
BANNED	S0		Chlorophenylpiperazine	Psychoactive	Lacks FDA approval.		
CONTROLLED	S7	A	Chloroprocaine	Local anesthetic	Nesacaine.		
BANNED	S0		Chloropyramine	Antihistamine	Lacks FDA approval.		

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BANNED	S5		Chlorothiazide	Diuretic	Diuril.		
BANNED	S0		Chlorphenesin	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Chlorphenesin	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	B	Chlorpheniramine	Antihistamine	ChlorTrimeton.		
BANNED	S0		Chlorphenoxamine	Antihistamine	Lacks FDA approval.		
BANNED	S0		Chlorphentermine	Stimulant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Chlorproethazine	Muscle relaxant	Lacks FDA approval.		
BANNED	S0		Chlorpromazine	Sedative	Generic.		
BANNED	S0		Chlorpropamide	Hypoglycemic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Chlorprothixene	Antipsychotic	Discontinued, no FDA-approved product commercially available.		
BANNED	S5		Chlorthalidone	Diuretic	Thalitone.		
BANNED	S0		Chlorthenoxazine	NSAID	Lacks FDA approval.		
BANNED	S5		Chlorthiazide (Chlorothiazide)	Diuretic	Diuril.		
CONTROLLED	S7	B	Chlorzoxazone	Muscle relaxant	Generic.		
CONTROLLED—fillies and mares.	S7	B	Chorionic Gonadotropin (CG)	Reproductive hormone	Pregnyl—biologic, does not require FDA approval.		
BANNED—intact males and geldings.	S2		Chorionic Gonadotropin (CG)	Reproductive hormone	Pregnyl.		
CONTROLLED	S7	C	Ciclesonide	Corticosteroid	Aservo EquiHaler, Alvesco	Detection Time: 48 hours. 5.5 mg/day × 5 days, then 4.1 mg/day × 5 days via inhalation (Aservo Equihaler). (6 horses).	
BANNED	S0		Cicloprofen	NSAID	Lacks FDA approval.		
BANNED	S0		Cilazapril	Anti-hypertensive	Lacks FDA approval.		
CONTROLLED	S7	B	Cilostazol	Vasodilator	Pletal.		
BANNED	S0		Cimaterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
BANNED	S3		Cimbuterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
CONTROLLED	S7	C	Cimetidine	Anti-ulcer	Tagamet	Restricted administration time: 24 hours. 20 mg/kg orally twice daily for a total of 7 doses (9 horses).	400 ng/mL in serum or plasma.
BANNED	S0		Cinchocaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Cinchophen	NSAID	Lacks FDA approval.		
BANNED	S0		Cinnarizine	Antihistamine	Lacks FDA approval.		
BANNED	S0		Citalopram	Antidepressant	Celexa.		
BANNED	S0		Clanobutin	Cholerectic	Lacks FDA approval.		
CONTROLLED	S7	B	Clemastine	Antihistamine	Tavist, Dayhist.		
BANNED	S0		Clemizole	Antihistamine	Lacks FDA approval.		
CONTROLLED	S7	B	Clenbuterol	Beta-2 agonist-bronchodilator	Ventipulmin	Treated horse Vet Listed for minimum 21 days after last treatment. Official Workout and Clearance Testing (blood and urine) required to re-establish eligibility to race. Dosing specification: 0.8 mcg/kg orally twice daily for up to 30 days total in a 6 month period.	

BANNED	S3		Clenpenterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
BANNED	S0		Clibucaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Clidinium	Anticholinergic	No FDA-approved product.		
BANNED	S0		Clobazam	Anxiolytic	Sympazan, Onfi. DEA Schedule IV.		
BANNED	S0		Clobenzorex	Stimulant	Lacks FDA approval.		
CONTROLLED	S7	C	Clobetaso	Corticosteroid	Olux, Cormax, Embeline, Impoyz, Clobex, Impeklo.		
CONTROLLED	S7	C	Clocortolone	Corticosteroid	Cloderm.		
BANNED	S6		Clodronate (Clodronic acid)	Bisphosphonate	OsPhos.		
BANNED	S5		Clofenamid	Carbonic Anhydrase Inhibitor	Lacks FDA approval.		
BANNED	S0		Clomethiazole (Chlormethiazole)	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S4		Clomifene	Induce ovulation	Generic.		
BANNED	S0		Clomipramine	Antidepressant	Clomicalm.		
BANNED	S0		Clonazepam	Anxiolytic	Klonopin. DEA Schedule IV.		
CONTROLLED	S7	A	Clonidine	Antihypertensive/Analgesic	Catapres-TTS.		
BANNED	S0		Clonixin	NSAID	Lacks FDA approval.		
BANNED	S5		Clopamide	Diuretic	Lacks FDA approval.		
BANNED	S0		Cloranolol	Antihypertensive	Lacks FDA approval.		
BANNED	S0		Clorazepate	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Clormecaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Clorprenaline	Bronchodilator	Lacks FDA approval.		
BANNED	S1		Clostebol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Clotiapine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Clotiazepam	Anxiolytic	Lacks FDA approval.		
BANNED	S0		Cloxazolam	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Clozapine	Antipsychotic	Clozaril, Versacloz.		
BANNED	S2		CNTO 530	Erythropoiesis	Lacks FDA approval.		
BANNED	S2		Cobalt Salts (*e.g.*, $CoCl_2$)	Erythropoiesis			Threshold: 0.1 mcg/mL total Cobalt in urine OR 0.025 mcg/mL total (free and protein bound)/mL in serum or plasma.
BANNED	S6		Cobratoxin, alpha	Neurotoxin	Lacks FDA approval.		
BANNED	S0		Cocaine (metabolite: benzoylecgonine).	Stimulant	Goprelto, Numbrino. DEA Schedule II.		
BANNED	S0		Codeine	Opioid Analgesic	Generic (DEA Schedule II or in combination with NSAIDs, caffeine and other drugs (DEA Schedule III).		
CONTROLLED	S7	B (x)	Colchicine	Anti-gout	Colcrys, Mitigare.		
BANNED	S0		Conorphone	Opioid Analgesic	Lacks FDA approval.		
BANNED	S2		Corticorelin	Corticosteroid stimulation	Approved Oprhan Drug.		
CONTROLLED	S7	B	Corticotrophin	Corticosteroid stimulation	ACTH–80, Acthar Gel.		
BANNED	S0		Cortivazol	Glucocorticoid	Lacks FDA approval.		
BANNED	S0		Cotinine (Cotinine is a metabolite of nicotine. If there is credible evidence that the presence of cotinine in a horse's sample is a consequence of nicotine exposure, the classification of cotinine may be revised to S7(A).).	Psychoactive/Anxiolytic	Lacks FDA approval.		
CONTROLLED	S7	C	Cromolyn (Cromoglycate)	Mast Cell Stabilizer	Gastrocrom.		
BANNED	S0		Cropropamide	Respiratory Stimulant	Lacks FDA approval.		
BANNED	S0		Crotethamide	Respiratory Stimulant	Lacks FDA approval.		
BANNED	S0		Cyamemazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Cyclandelate	Vasodilator	Lacks FDA approval.		
BANNED	S0		Cyclizine	Antihistamine	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Cyclobarbital	Barbiturate	Lacks FDA approval.		
CONTROLLED	S7	B	Cyclobenzaprine	Muscle relaxant	Flexeril, Amrix.		

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BANNED	S4		Cyclofenil	Selective Estrogen Receptor Modulator (SERM).	Lacks FDA approval.		
BANNED	S0		Cycloguanil	Antimalarial	Lacks FDA approval.		
BANNED	S0		Cyclomethycaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Cyclopentamine	Vasoconstrictor	Lacks FDA approval.		
CONTROLLED	S7		Cyclopentolate	Mydriatic	Akpentolate, Cyclogyl, Pentolair, Cyclomydril.		
BANNED	S0		Cyclophenil	Selective Estrogen Receptor Modulator (SERM).	Lacks FDA approval.		
BANNED	S0		Cyclothiazide	Diuretic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Cycrimine	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	B	Cyproheptadine	Antihistamine	Periactin.		
BANNED	S4		Dalantercept (ACE–041)	Anti-neoplastic	Lacks FDA approval.		
BANNED	S1		Danazol	Anabolic	Generic.		
CONTROLLED	S7	C	Dantrolene	Muscle relaxant	Dantrium	Detection Time: 48 hrs. 500 mg orally once daily for 3 days. (12 horses).	3 ng/mL of 5-hydroxydantrolene in urine; 0.1 ng/mL in serum or plasma as 3′-hydroxydantrolene.
BANNED	S2		Darbepoetin (dEPO)	Erythropoiesis	Aranesp.		
BANNED	S0		Decamethonium	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
BANNED	S1		Dehydrochloromethylte stosterone.	Anabolic	Turinabol. DEA Schedule III.		
BANNED	S0		Delmadinone acetate	Reproductive hormone	Lacks FDA approval.		
BANNED	S0		Delorazepam	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Dembroxol (Dembrexine)	Mucolytic	Lacks FDA approval.		
BANNED	S0	(x)	Demecolcine	Anti-neoplastic/ Immunomodulator.	Lacks FDA approval.		
BANNED	S0		Demoxepam	Anxiolytic	Lacks FDA approval.		
BANNED	S0		Deoxycorticosterone	Minerlocorticoid	Lacks FDA approval.		
BANNED	S0		Deptropine	Antihistamine	Lacks FDA approval.		
CONTROLLED	S7	B	Deracoxib	NSAID	Deramaxx.		
BANNED	S6		Dermorphin	Opioid Receptor Agonist	Lacks FDA approval.		
BANNED	S0		Deserpidine	Antihypertensive	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Desipramine	Antidepressant	Norpramin.		
CONTROLLED—Fillies and Mares.	S7	B	Deslorelin	Induce ovulation	Ovuplant, SucroMate, Suprelorin.		
BANNED—intact males and geldings.	S4		Deslorelin	Reproductive hormone	Ovuplant, SucroMate, Suprelorin.		
BANNED	S5		Desmopressin	Anti-diuretic	DDAVP, Nocdurna.		
CONTROLLED	S7	C	Desonide	Corticosteroid	Verdeso, Desowen.		
CONTROLLED	S7	C	Desoximethasone (desoxymethasone, desoximetasone).	Corticosteroid	Topicort.		
BANNED	S1		Desoxymethyltestosterone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Desoxyvinyl-testosterone	Anabolic	Lacks FDA approval.		
CONTROLLED	S7	B	Detomidine	Sedative/Analgesic	Dormosedan	Detection Time: 48 hrs. 0.02 mg/kg single IV dose (10 horses).	2 ng/mL 3-carboxydetomidine in urine; 0.02 ng/mL in serum or plasma.
CONTROLLED	S7	C	Dexamethasone	Corticosteroid	Azium, Dexasone	Detection Time: 72 hours. Single 20 mg IV, IM, or oral dose (20 horses).	0.2 ng/mL in urine.

CONTROLLED	S7	C	Dexamethasone Sodium phosphate.	Corticosteroid	Generic	Detection Time: 72 hours. 0.06 mg/kg single IV dose (6 horses).	
CONTROLLED	S7	B	Dextromethorphan	Antitussive	Delsym, Robitussin.		
BANNED	S0		Dextromoramide	Opioid Analgesic	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Dextropropoxyphene	Opioid Analgesic	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
BANNED	S0		Dextrorphan (Dextrorphan may be present as a metabolite of dextromethorphan. If there is credible evidence that the presence of dextrorphan in the horse's sample is the consequence of dextromethorphan administration, the classification of dextrorphan may be revised to S7(A).).	Psychoactive/Antitussive	Lacks FDA approval.		
BANNED	S0		Dezocine	Opioid Analgesic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Diacerein	Anti-osteoarthritic	Lacks FDA approval.		
BANNED	S0		Diamorphine (diacetylmorphine)	Opioid Analgesic	Lacks FDA approval. DEA Schedule I.		
CONTROLLED	S7	B	Diazepam	Anxiolytic	Valium. DEA Schedule IV.		
BANNED	S0		Diazoxide	Antihypertensive/Hyperglycemic	Proglycem.		
BANNED	S0		Dibenzepin	Antidepressant	Lacks FDA approval.		
BANNED	S0		Dibucaine	Local anesthetic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Dichlorisone	Corticosteroid	Lacks FDA approval.		
BANNED	S0		Dichloroacetate	Anti-neoplastic	Lacks FDA approval.		
CONTROLLED	S7	C	Dichlorphenamide	Carbonic Anhydrase Inhibitor	Keveyis.		
CONTROLLED	S7	C	Diclofenac	NSAID	Surpass, Voltaren		50 ng/mL in urine.
BANNED	S0		Dicumarol	Anticoagulant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Diethylpropion	Stimulant	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Diethylthiambutene	Opioid Analgesic	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Diethyltryptamine (DET)	Hallucinogen	Lacks FDA approval.		
CONTROLLED	S7	C	Diflorasone	Corticosteroid	Florone.		
BANNED	S0		Diflucortolone	Corticosteroid	Lacks FDA approval.		
BANNED	S0		Diflunisal	NSAID	Generic.		
BANNED	S0		Digitoxin	Antiarrhythmic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	B	Digoxin	Antiarrhythmic	Lanoxin.		
BANNED	S0		Dihydrocodeine	Opioid Analgesic	Trezix (with acetaminophen and caffeine) DEA Schedule III.		
BANNED	S0		Dihydrocodeinone	Opioid Analgesic	Lacks FDA approval.		
CONTROLLED	S7	B	Dihydroergotamine mesylate	Ergot alkaloid	Migranal, Trudhesa.		
BANNED	S0		Dihydromorphine	Opioid Analgesic	Lacks FDA approval. DEA Schedule I.		
BANNED	S1		Dihydrotestosterone (17β-hydroxy- 5a androstan-3-one, Androstanolone).	Anabolic	Anabolex, Andractimm, Pesomax, Stanolone. DEA Schedule III.		
BANNED	S0		Diisopropylamine	Vasodilator	Lacks FDA approval.		
BANNED	S0		Diltiazem	Antihypertensive	Cardizem CD, Taztia XT, Tiazac.		
BANNED	S0		Dimefline	Respiratory Stimulant	Lacks FDA approval.		
BANNED	S0		Dimethindene	Antihistamine	Lacks FDA approval.		
BANNED	S0		Dimethisoquin (quinocaine)	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Dimethylamphetamine	Stimulant	Lacks FDA approval.		
BANNED	S0		Dimethylphenidate	Stimulant	Lacks FDA approval.		

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CONTROLLED	S7	C	Dimethylsulfoxide (DMSO)	NSAID	Domoso	Detection Time: 48 hrs. 70 mL 90% DMSO in 500 mL LRS IV single administration (30 horses).	15 mcg/mL in urine or 1,000 ng/mL in serum or plasma. *Note:* The detection of more than one NSAID in a horse's post-Race or Post-Official Workout blood sample constitutes a Stacking Violation.
BANNED	S0	(x)	Dimethyltryptamine (DMT)	Hallucinogen	Lacks FDA approval. DEA Schedule I.		Threshold: 10 mcg/mL total (free and conjugated) in urine.
BANNED	S0		Diphenadione	Anticoagulant	No FDA-approved product. Rodenticide.		
CONTROLLED	S7	B	Diphenhydramine	Antihistamine	Benadryl.		
CONTROLLED	S7	B	Diphenoxylate	Anti-diarrheal	DEA Schedule II. Lomotil (with atropine), DEA Schedule II.		
BANNED	S0		Diphenylpyraline	Antihistamine	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Dipipanone	Opioid Analgesic	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Diprenorphine	Narcotic antagonist	M50–50.		
BANNED	S0		Diprophylline	Bronchodilator	Lacks FDA approval.		
CONTROLLED	S7	B	Dipyridamole	Platelet inhibitor	Persantine.		
CONTROLLED	S7	C	Dipyrone	NSAID/Anti-pyretic	Zimeta	Detection Time: 72 hrs. 30 mg/kg single IV dose (10 horses).	1,000 ng/mL of 4-methylaminoantipyrine in urine. *Note:* The detection of more than one NSAID in a horse's post-Race or Post-Official Workout blood sample constitutes a Stacking Violation.
CONTROLLED	S7	B	Disopyramide	Antiarrhythmic	Norpace, Rythmodan.		
BANNED	S0		Disulfiram	Alcohol antagonist	Generic.		
BANNED	S0		Divalproex	Anticonvulsant	Depakote.		
BANNED	S0		Dixyrazine	Antipsychotic	Lacks FDA approval.		
CONTROLLED	S7	B	Dobutamine	Beta-1 agonist	Generic.		
BANNED	S4		Domagrozumab	Anabolic	Lacks FDA approval.		
BANNED	S0		Donepezil	Behavior and Cognitive Modifier	Adilarity, Aricept.		
CONTROLLED	S7	A	Dopamine	Neurotransmitter	Generic.		
BANNED	S0		Dopexamine	Vasodilator	Lacks FDA approval.		
CONTROLLED	S7	B	Dorzolamide	Carbonic Anhydrase Inhibitor	Cosopt.		
BANNED	S0		Dothiepin	Antidepressant	Lacks FDA approval.		
BANNED	S0		Doxacurium	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	A	Doxapram	Respiratory Stimulant	Dopram, Respiram.		
BANNED	S0		Doxazosin	Antihypertensive	Cardura.		
BANNED	S0		Doxefazepam	Anxiolytic	Lacks FDA approval.		
CONTROLLED	S7	A	Doxepin	Antidepressant	Generic.		
CONTROLLED	S7	B	Doxylamine	Antihistamine	Unisom.		
BANNED	S1		Dromostanolone (drostanolone)	Anabolic	Lacks FDA approval.		
BANNED	S0		Droperidol	Antipsychotic	Inapsine.		
BANNED	S0		Drospirenone	Reproductive hormone	Slynd, Nextstellis, Angeliq, Lo-Zumandimine, Loryna, elamisa, Nikki, Yaz.		
BANNED	S0		Duloxetine	Antidepressant	Cymbalta, Drizalma.		
CONTROLLED	S7	C	Dyclonine	Topical anesthetic	Dyclopro.		

BANNED	S0		Dyphylline (Diphylline)	Antipsychotic/Antiemetic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Edrophonium	Muscle strengthener	Discontinued, no FDA-approved product commercially available.		
BANNED	S2		Efaproxiral (RSR13)	Hemoglobin modifier	FDA orphan drug.		
BANNED	S0		Eletripan	Selective Serotonin Receptor Agonist.	Relpax.		
BANNED	S0		Eltenac	NSAID	Lacks FDA approval.		
BANNED	S0		Embramine	Antihistamine	Lacks FDA approval.		
BANNED	S0		Embutramide	Opioid Analgesic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Emepronium	Antispasmodic	Lacks FDA approval.		
BANNED	S0		Emidonol	Anti-inflammatory	Lacks FDA approval.		
BANNED	S0		Enalapril (metabolite enaloprilat)	Angiotensin-converting enzyme inhibitor.	Vasotec.		
BANNED	S0		Enciprazine	Anxiolytic/Antipsychotic	Lacks FDA approval.		
CONTROLLED	S7	A	Ephedrine	Stimulant	Akovaz, Corphedra, Emerphed.		
BANNED	S6		Epibatidine	Analgesic	Lacks FDA approval.		
BANNED	S1		Epi-dihydrotestosterone	Anabolic	Lacks FDA approval. DEA Schedule III.		
CONTROLLED	S7	A	Epinephrine	Stimulant	Adrenalin, Epipen, Adrenaclick, Auvi-Q, Symjepi, Primatene Mist.		
BANNED	S1		Epitestosterone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Eplerenone	Antihypertensive	Inspra.		
BANNED	S2		EPO-based constructs (*e.g.,* EPO-Fc).	Erythropoiesis	Lacks FDA approval.		
BANNED	S2		EPO-mimetic agents (*e.g.,* CNTO–530, peginesatide).	Erythropoiesis.			
BANNED	S0		Ergonovine	Ergot alkaloid	Lacks FDA approval.		
BANNED	S0	(x)	Ergotamine	Ergot alkaloid	Ergomar, Migergot (with caffeine).		
BANNED	S0		Erythritol tetranitrate	Vasodilator	Lacks FDA approval.		
BANNED	S2		Erythropoietin (EPO)	Erythropoiesis.			
BANNED	S0		Esmolol	Antihypertensive	Brevibloc.		
CONTROLLED	S7	C	Esomeprazole	Anti-ulcer	Nexium.		
BANNED	S0		Estazolam	Sedative/Anti-convulsant	Prosom. DE Schedule IV.		
CONTROLLED—in male horses (other than geldings).	S7	B	Estranediol	Estrogen			Threshold: 0.045 mcg/mL total (free and conjugated) 5α-estrane-3β, 17α-diol per millilitre in urine when, at screening, the total 5α-estrane-3β, 17α-diol exceeds the total 5,10 estrene-3β,17α-diol in urine.
BANNED	S0		Eszopiclone	Hypnotic	Lunesta.		
BANNED	S0		Etafedrine	Bronchodilator	Lacks FDA approval.		
BANNED	S0		Etamiphylline	Respiratory Stimulant	Lacks FDA approval.		
BANNED	S0		Etamivan (Ethamivan)	Respiratory Stimulant	Lacks FDA approval.		
CONTROLLED	S7	B	Etanercept	NSAID	Enbrel.		
BANNED	S5		Ethacrynic acid (Etacrynic acid)	Diuretic	Edecrin.		
BANNED	S0		Ethamivan	Respiratory Stimulant	Lacks FDA approval.		
BANNED	S0		Ethamsylate	Antihemorrhagic	Lacks FDA approval.		
BANNED	S0		Ethanol	Depressant	Grain alcohol, Everclear.		
BANNED	S0		Ethaverine	Vasodilator	Lacks FDA approval.		
BANNED	S0		Ethchlorvynol	Sedative/Hypnotic	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
BANNED	S0		Ethiazide	Diuretic	Lacks FDA approval.		
BANNED	S0		Ethinamate	Sedative/Hypnotic	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
BANNED	S0		Ethinylestradiol	Reproductive hormone	Lacks FDA approval.		
BANNED	S0		Ethoheptazine	Analgesic	Lacks FDA approval.		

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BANNED	S0		Ethopropazine	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Ethopropazine	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Ethosuximide	Anticonvulsant	Zarontin.		
BANNED	S0		Ethotoin	Anticonvulsant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Ethoxzolamide	Carbonic Anhydrase Inhibitor	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Ethyl isobutrazine	Sedative	Lacks FDA approval.		
BANNED	S0		Ethyl Loflazepate	Sedative Anxiolytic	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
CONTROLLED	S7	C	Ethylaminobenzoate (Benzocaine).	Local anesthetic	Orajel.		
BANNED	S0		Ethylamphetamine	Stimulant	Lacks FDA approval.		
BANNED	S1		Ethylestrenol	Anabolic	Discontinued, no FDA-approved product commercially available. DEA Schedule III.		
BANNED	S0		Ethylmorphine	Opioid Analgesic	Lacks FDA approval. DEA Schedule II.		
BANNED	S0		Ethylnorepinephrine	Stimulant	Lacks FDA approval.		
BANNED	S0		Ethylphenidate	Stimulant	Lacks FDA approval.		
BANNED	S0		Etidocaine	Local anesthetic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Etifoxine	Anticonvulsant	Lacks FDA approval.		
BANNED	S0		Etifoxine (etafenoxine)	Anticonvulsant	Lacks FDA approval.		
BANNED	S0		Etilefrine	Stimulant	Lacks FDA approval.		
BANNED	S0		Etiocholanolone	Anabolic	Lacks FDA approval.		
BANNED	S0		Etizolam	Anxiolytic	Lacks FDA approval.		
CONTROLLED	S7	B	Etodolac	NSAID	Generic.		
BANNED	S0		Etodroxizine	Antihistamine	Lacks FDA approval.		
BANNED	S0		Etofenamate	NSAID	Lacks FDA approval.		
BANNED	S0		Etomidate	Anesthetic	Amidate.		
BANNED	S0		Etoricoxib	NSAID	Lacks FDA approval.		
BANNED	S0		Etorphine HCl	Opioid analgesic	M99. DEA Schedule II.		
BANNED	S2		Examorelin (hexarelin)	Growth Hormone	Lacks FDA approval.		
BANNED	S4		Exemestane	Aromatase inhibitor	Aromasin.		
CONTROLLED	S7	C	Famotidine	Anti-ulcer	Duexis, Pepcid.		
BANNED	S0		Famprofazone	NSAID	Lacks FDA approval.		
BANNED	S0		Febarbamate	Anxiolytic	Lacks FDA approval.		
BANNED	S0		Felbamate	Anticonvulsant	Trezix, Tuxari, Triacin-C.		
BANNED	S0		Felbinac	NSAID	Lacks FDA approval.		
BANNED	S0		Felodipine	Antihypertensive	Generic.		
BANNED	S0		Fenbufen	NSAID	Felbatol.		
BANNED	S0		Fenbutrazate	Psychostimulant	Lacks FDA approval.		
BANNED	S0		Fencamfamine	Stimulant	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Fencamine	Psychostimulant	Lacks FDA approval.		
BANNED	S0		Fenclofenac	NSAID	Lacks FDA approval.		
BANNED	S0		Fenclozic acid	NSAID	Lacks FDA approval.		
BANNED	S0		Fenetylline (fenetylline, phenethylline, phenetylline).	Psychostimulant	Lacks FDA approval.		
BANNED	S0		Fenfluramine	Stimulant	Fintepla. DEA Schedule IV.		
CONTROLLED	S7	B	Fenoldopam	Vasodilator	Corlopam.		
CONTROLLED	S7	B	Fenoprofen	NSAID	Nalfon.		
BANNED	S3		Fenoterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
BANNED	S0		Fenozolone	Psychostimulant	Lacks FDA approval.		
BANNED	S0		Fenpiprane	Antispasmodic	Lacks FDA approval.		

BANNED	S0		Fenproporex	Stimulant	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Fenspiride	Bronchodilator	Lacks FDA approval.		
CONTROLLED	S7	A	Fentanyl (fentanil)	Opioid Analgesic	Actiq, Fentora, Lazanda, Sublimaze, Subsys. DEA Schedule II.		
BANNED	S0		Fentiazac	NSAID	Lacks FDA approval.		
BANNED	S0		Feprazone	NSAID	Lacks FDA approval.		
CONTROLLED	S7	C	Fexofenadine	Antihistamine	Allegra.		
BANNED	S2		Fibroblast Growth Factors (FGFs).	Growth Hormone.			
CONTROLLED	S7	C	Firocoxib	NSAID	Equioxx, Previcox	Detection Time: 360 hrs. 100 mcg/kg orally once daily for total of 7 doses. (20 horses).	2 ng/mL in serum or plasma.
BANNED	S0		Flavoxate	Anticholinergic	Generic.		
CONTROLLED	S7	B	Flecainide	Antiarrhythmic	Generic.		
BANNED	S0		Floctafenine	NSAID	Lacks FDA approval.		
BANNED	S0		Fluanisone	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Fludiazepam	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Fludrocortisone	Corticosteroid	Generic.		
BANNED	S0		Flufenamic acid	NSAID	Lacks FDA approval.		
CONTROLLED	S7	C	Flumethasone (flumetasone)	Corticosteroid	Flucort, Anaprime.		
BANNED	S5		Flumethiazide	Diuretic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Flunarizine	Calcium channel blocker	Lacks FDA approval.		
BANNED	S0		Flunisolide	Corticosteroid	Generic.		
BANNED	S0		Flunitrazepam	Sedative/Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
CONTROLLED	S7	C	Flunixin	NSAID (3 NSAIDs (Flunixin, Ketoprofen, Phenylbutazone) are associated with a Detection Time of 48 hours. Only one of the three may be administered using a Withdrawal Interval based on the 48 hour Detection Time. To avoid a stacking violation (detection of more than 1 NSAID in a blood sample) the following secondary Detection Times should be applied for the following 3 NSAIDs: Flunixin: 144 hours; Ketoprofen 96 hours; Phenylbutazone: 168 hours.).	Banamine, Flunixamine, Equileve, Meflosyl.	Detection Time: 48 hrs. 1.1 mg/kg single IV dose (16 horses); 500 mg single IV dose (12 horses).	4 ng/mL in serum or plasma. *Note:* The detection of more than one NSAID in a horse's post-Race or Post-Official Workout blood sample constitutes a Stacking Violation.
CONTROLLED	S7	C	Fluocinolone acetonide	Corticosteroid	Flucort-N.		
CONTROLLED	S7	C	Fluocinonide	Corticosteroid	Fluonex, Lidex, Lonide, Lyderm.		
BANNED	S0		Fluocortolone	Corticosteroid	Lacks FDA approval.		
BANNED	S0		Fluopromazine (Triflupromazine)	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Fluoresone	Anticonvulsant	Lacks FDA approval.		
BANNED	S0		Fluorocortisone	Corticosteroid	Lacks FDA approval.		
CONTROLLED	S7	C	Fluorometholone	Corticosteroid	FML Forte.		
BANNED	S0		Fluorophenethylamine	Stimulant	Lacks FDA approval.		
BANNED	S0		Fluoroprednisolone	Corticosteroid	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Fluoxetine	Antidepressant	Prozac.		
BANNED	S1		Fluoxymesterone	Anabolic	Discontinued, no FDA-approved product commercially available. DEA Schedule III.		
BANNED	S0		Flupenthixol (flupentixol)	Antipsychotic	Lacks FDA approval.		
CONTROLLED	S7	B	Fluphenazine	Antipsychotic	Generic.		
BANNED	S0		Flupirtine	Analgesic	Lacks FDA approval.		
BANNED	S0		Fluprednisolone	Corticosteroid	Discontinued, no FDA-approved product commercially available.		

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CONTROLLED	S7	C	Flurandrenolide (Flurandrenolone, Fludroxycortide).	Corticosteroid	Cordran.		
BANNED	S0		Flurazepam	Sedative/Anxiolytic	Generic. DEA Schedule IV.		
CONTROLLED	S7	B	Flurbiprofen	NSAID	Ansaid, Ocufen, Strepfen.		
BANNED	S0		Fluspirilene	Antipsychotic	Lacks FDA approval.		
CONTROLLED	S7	C	Fluticasone	Corticosteroid	Flovent, Flonase.		
BANNED	S0		Flutoprazepam	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Fluvoxamine	Antidepressant	Luvox.		
BANNED	S4		Follistatin	Myostatin inhibitor.			
BANNED	S1		Formebolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S4		Formestane	Aromatase inhibitor	Lacks FDA approval.		
BANNED	S3		Formoterol (Aformoterol)	Beta-2 agonist-bronchodilator	Brovana; Breyna (with budesonide); Duaklir Pressair (with aclidinium).		
BANNED	S0		Fosinopril	Antihypertensive	Generic.		
BANNED	S0		Fosphenytoin	Anticonvulsant	Cerebyx.		
BANNED	S4		Fulvestrant	Estrogen antagonist	Falsodex.		
BANNED	S1		Furazabol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Furazadrol	Anabolic	Lacks FDA approval.		
BANNED	S0		Furfenorex	Stimulant	Lacks FDA approval.		
CONTROLLED-(Permitted at all times during Workouts, Official Workouts, and other training exercise).	S7	C	Furosemide	Diuretic	Lasix, Salix	Restricted Administration: 48 hrs. 1 mg/kg single IV dose (6 horses).	50 ng/mL in urine or 0.1 ng/mL in serum or plasma.
CONTROLLED-where permitted on race day.	S7	C	Furosemide (where permitted by exemption).	Diuretic	Lasix, Salix	Shall not be administered within 4 hours prior to Post-Time.	100 ng/mL in serum or plasma AND urine S.G. >1.010.
CONTROLLED	S7	B	Gabapentin	Anticonvulsant	Horizant, Gralise, Neurontin.		
BANNED	S0		Galantamine	Acetylcholinesterase inhibitor	Razadyne.		
BANNED	S0		Gallamine	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Gamma Aminobutyric Acid (GABA).	Neurotransmitter	Endogenous substance.		
BANNED	S0		Gamma-butyrolactone (GBL)	Neurohormone	Lacks FDA approval.		
BANNED	S0		Gamma-hydroxybutyrate (GHB)	CNS depressant	Lacks FDA approval.		
BANNED	S0		Gepirone	Antidepressant	Lacks FDA approval.		
BANNED	S1		Gestrinone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		GH-Releasing Peptides (ghrps), *e.g.,* alexamorelin, GHRP–6, hexarelin and pralmorelin (GHRP–2).	Growth Hormone.			
BANNED	S0	(x)	Glaucine	Antitussive (cough suppressant)	Lacks FDA approval		0.5 ng/mL in serum or plasma.
BANNED	S0		Glutethimide (chlorhexidol)	Sedative	Discontinued, no FDA-approved product commercially available. DEA Schedule II.		
CONTROLLED	S7	C	Glycopyrrolate	Anticholinergic	Robinul	Detection Time: 48 hours. 1 mg single dose IV. (20 horses).	0.003 ng/mL in serum or plasma.
CONTROLLED—fillies and mares.	S7	B	Gonadorelin	Induce ovulation	Cystorelin, Factrel, Fertelin, OvaCyst, Fertagyl, Gonabreed.		
BANNED—intact males and geldings.	S4		Gonadorelin	Reproductive hormone modulator.	Cystorelin, Factrel, Fertelin, OvaCyst, Fertagyl, Gonabreed.		

BANNED	S2		Goserelin	Reproductive hormone modulator.	Zoladex.		
BANNED	S1		Growth Hormone Releasing Hormone (GHRH).	Anabolic.			
CONTROLLED	S7	C	Guaifenesin (glycerol guiacolate).	Expectorant	Mucinex	Detection Time: 48 hrs. 2 grams total body dose, orally twice daily for 5 doses. (9 horses).	1 ng/mL in serum or plasma.
BANNED	S0			Antihypertensive	Generic.		
BANNED	S0		Guanadrel	Antihypertensive	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Guanethidine	Antihypertensive	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Guanoclor	Antihypertensive	Lacks FDA approval.		
BANNED	S0		Halazepam	Sedative/Anxiolytic	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
CONTROLLED	S7	C	Halcinonide	Corticosteroid	Halog.		
BANNED	S0		Haldrol	Anabolic	Lacks FDA approval.		
CONTROLLED	S7	C	Halobetasol	Corticosteroid	Lexette, Bryhali, Ultravate.		
BANNED	S0		Haloperidol	Antipsychotic	Haldol.		
BANNED	S0		Haloxazolam	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Harmaline	Psychoactive	Lacks FDA approval.		
CONTROLLED	S7	B	Harpagoside (Devil's Claw)	Anti-inflammatory	Glycoside of plangt origin. No FDA-approved products commercially available. Constituent of multiple, unregulated OTC herbal remedies.		
BANNED	S2		Hepatocyte Growth Factor (HGF).	Growth Hormone.			
BANNED	S0		Heptaminol	Cardiac stimulant.			
BANNED	S0		Hexafluorenium	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Hexobarbital	Sedative	Lacks FDA approval.		
BANNED	S0		Hexocyclium	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Hexylcaine	Local anesthetic	Discontinued, no FDA-approved product commercially available.		
BANNED	S3		Higenamine (norclaurine, demethylcoclaurine).	Bronchodilator	Constituent of numerous OTC dietary supplements marketed for weight loss or as sports/energy supplements. Lacks FDA approval.		
BANNED	S0		Histapyrrodine	Antihistamine	Lacks FDA approval.		
BANNED	S4		Histrelin	GnRH agonist	Supprelin LA, Vantas.		
CONTROLLED	S7	B	Homatropine	Anticholinergic	Hycodan [with hydrocodone].		
BANNED	S0		Homophenazine	Antipsychotic	Lacks FDA approval.		
CONTROLLED	S7	A (x)	Hordenine	Stimulant	Plant alkaloid (*e.g.,* barley). Constituent of numerous OTC dietary supplements marketed for weight loss. Lacks FDA approval.		80 mcg/mL total (free and conjugated) in urine.
CONTROLLED	S7	B	Hydralazine	Vasodilator	Hydra-Zide, Bidil.		
BANNED	S5		Hydrochlorthiazide	Diuretic	Lotensin (with bisoprolol); Vaseretic (with enalapril); Avilide (with irbesartan); Zestoretic (with lisinopril); Lopressor (with metoprolol); Micardis (with telmisartan); and others.		
BANNED	S0		Hydrocodone (dihydrocodienone).	Opioid Analgesic	Hysingla; Apadaz, Anexsia (with acetaminophen); Hycodan (with homatropine) DEA Schedule II.		

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CONTROLLED	S7	C	Hydrocortisone	Corticosteroid	Cortef. *Note:* hydrocortisone is a component of numerous products, particularly those for topical, ophthalmic, and otic applications. The Responsible Person is advised to read all medication labels prior to authorizing administration..		Threshold: 1 mcg/mL in urine.
BANNED	S5		Hydroflumethiazide	Diuretic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Hydromorphinol	Opioid Analgesic	Lacks FDA approval.		
BANNED	S0		Hydromorphone	Opioid Analgesic	Dilaudid. DEA Schedule II.		
BANNED	S0		Hydroxyamphetamine	Stimulant	Paremyd (with tropicamide).		
BANNED	S0		Hydroxy-gamma amino butyric acid.	Neurohormone	Lacks FDA approval.		
BANNED	S0		Hydroxytestosterone	Anabolic	Lacks FDA approval.		
CONTROLLED	S7	C	Hydroxyzine	Antihistamine	Atarax	Detection time: 96 hours. Hydroxyzine: 190 mg twice daily for a total of 9 doses (2 horses).	
BANNED	S6		Ibandronate	Bisphosphonate	Generic.		
BANNED	S0		Ibogaine	Psychoactive	Lacks FDA approval. DEA Schedule I.		
CONTROLLED	S7	C	Ibuprofen	NSAID	Advil, Motrin.		
BANNED	S2		Ibutamoren	Growth Hormone	Investigational New Drug (in clinical trials).		
CONTROLLED	S7	B	Ibutilide	Antiarrhythmic	Corvert.		
BANNED	S0		Iloprost	Vasodilator	Ventavis.		
CONTROLLED	S7	A	Imipramine	Antidepressant	Tofranil.		
BANNED	S3		Indacaterol	Beta-2 agonist-bronchodilator	Discontinued, no FDA-approved product commercially available.		
BANNED	S5		Indapamide	Diuretic	Generic.		
CONTROLLED	S7	B	Indomethacin	NSAID	Indocin.		
BANNED	S0		Indoprofen	NSAID	Lacks FDA approval.		
BANNED	S0		Indoramin	Antihypertensive	Lacks FDA approval.		
CONTROLLED	S7	B	Infliximab	Immunosuppressor	Remicade.		
BANNED	S2		Insulin- like Growth Factor-1 (IGF–1) and its analogues.	Peptide hormone.			
BANNED	S2		Insulins	Anti-hyperglycemics.			
BANNED	S2		IOX–2	Erythropoiesis	Lacks FDA approval.		
BANNED	S2		Ipamorelin	Growth Hormone	Lacks FDA approval.		
CONTROLLED	S7	B	Ipratropium	Bronchodilator	Atrovent	Detection Time: 120 hrs. 5.5 mcg/kg once daily via nebulization for 3 total doses (6 horses).	0.25 ng/mL in urine.
CONTROLLED	S7	B	Ipratropium bromide	Bronchodilator	Atrovent; Combivent (with albuterol).		
BANNED	S0		Iprindole	Antidepressant	Lacks FDA approval.		
BANNED	S0		Iproniazid	Antidepressant	Lacks FDA approval.		
BANNED	S0		Ipsapirone	Antidepressant	Lacks FDA approval.		
BANNED	S0		Irbesartan	Antihypertensive	Avalide, Avapro.		
BANNED	S5		Irbesartan	Antihypertensive	Avalide, Avapro.		
BANNED	S0		Isoaminile	Antitussive	Lacks FDA approval.		
BANNED	S0		Isocarboxazid	Antidepressant	Marplan.		
BANNED	S0		Isoetharine	Bronchodilator	Discontinued, no FDA-approved product commercially available.		

CONTROLLED	S7	C	Isoflupredone	Corticosteroid	Predef 2x	14 day stand down for all intra-articular injections. Serum concentrations associated with an experimental dose of 8 mg IA single joint (6 horses) were all below Limit of Detection by 14 days.	
BANNED	S0		Isomethadone (isoamidone)	Synthetic opioid analgesic	Lacks FDA approval. DEA Schedule II.		
BANNED	S0		Isometheptene	Sympathomimetic	Lacks FDA approval.		
BANNED	S0		Isopropamide	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
BANNED	S3		Isoproterenol	Beta-2 agonist	Generic.		
BANNED	S0		Isopyrin (Raminfenazone)	NSAID	Lacks FDA approval.		
CONTROLLED	S7	B	Isosorbide dinitrate	Vasodilator	Isordil.		
BANNED	S0		Isothipendyl	Antihistamine	Lacks FDA approval.		
BANNED	S0		Isoxicam	NSAID	Lacks FDA approval.		
BANNED	S0		Isradipine	Antihypertensive	Generic.		
BANNED	S0		Isoxsuprine	Vasodilator	Lacks FDA approval.		
BANNED	S0		Kebuzone	NSAID	Lacks FDA approval.		
CONTROLLED	S7	B	Ketamine/norketamine	Anesthetic	Ketaset, Vetalar. DEA Schedule III.		
BANNED	S0		Ketazolam	Sedative/Anxiolytic	Lacks FDA approval. DEA Schedule IV.F722.		
CONTROLLED	S7	C	Ketoprofen	NSAID	Ketofen	Detection Time: 48 hrs. 2.2 mg/kg single IV dose. (24 horses).	4 ng/mL in serum or plasma. *Note:* The detection of more than one NSAID in a horse's post-Race or Post-Official Workout blood sample constitutes a Stacking Violation. 3 NSAIDs (Flunixin, Ketoprofen, Phenylbutazone) are associated with a Detection Time of 48 hours. Only one of the three may be administered using a Withdrawal Interval based on the 48 hour Detection Time. To avoid a stacking violation (detection of more than 1 NSAID in a blood sample) the following secondary Detection Times should be applied for the following NSAIDs: Flunixin: 144 hours; Ketoprofen 96 hours; Phenylbutazone: 168 hours.
CONTROLLED	S7	A	Ketorolac	NSAID	Acular, Acuvail, Sprix, Omidria.		
CONTROLLED	S7	B	Ketotifen	Antihistamine	Alaway, Zaditor.		
BANNED	S2		Krypton	Hypoxia Inducible Factor activating.			
BANNED	S0		Labetalol	Antihypertensive	Trandate.		
CONTROLLED	S7	A	Lamotrigine	Anticonvulsant	Lamictal.		
BANNED	S4		Landogrozumab	Myostatin inhibitor	Lacks FDA approval.		
CONTROLLED	S7	C	Lansoprazole	Anti-ulcer	Prevacid.		
BANNED	S2		Lenomorelin (ghrelin)	Growth Hormone	Lacks FDA approval.		
BANNED	S0		Lenperone	Antipsychotic	Lacks FDA approval.		

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit*
BANNED	S0		Leptazole (Pentylenetetrazole)	Stimulant	Lacks FDA approval.		
BANNED	S0		Letosteine	Mucolytic	Lacks FDA approval.		
BANNED	S2		Letrozole	Aromatase inhibitor	Femara.		
BANNED	S2		Leuprorelin (leuprolide)	Reproductive hormone modulator.	Eligard Kit, Fensolvi Kit, Camcevi Kit.		
BANNED	S0		Levallorphan	Opioid Antagonist	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	B	Levamisole	Anthelmintic/Immunostimulant	Ripercol, Tramisol, Levasole, Prohibit, LevaMed.		
BANNED	S0		Levobunolol	Antihypertensive	Betagan.		
BANNED	S0		Levocabastine	Antihistamine	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Levodopa	Decarboxylase Inhibitor	Inbrija; Stalevo, Rytary, Duopa, Dhivy, Sinemet (all with carbidopa).		
BANNED	S0		Levomethadone	Opioid Analgesic	Lacks FDA approval.		
BANNED	S0		Levomethorphan	Opioid Analgesic	Lacks FDA approval. DEA Schedule II.		
BANNED	S0		Levophacetoperane	Psychostimulant	Lacks FDA approval.		
BANNED	S0		Levorphanol	Opioid Analgesic	Generic. DEA Schedule II+F755.		
BANNED	S3		Levosalbutamol (levalbuterol)	Beta-2 agonist-bronchodilator	Xopenex.		
BANNED	S4		Levothyroxine	Metabolic hormone	Thyro-Tabs, ThyroKare, Tirosint, Ermeza,Euthyrox, Levolet, Synthroid, Levoxyl, Unithroid.		
CONTROLLED	S7	B	Lidocaine	Local anesthetic	Xylocaine [with epinephrine], Lignospan, Ztlido, Akten.	Detection Time: 48 hours. 200 mg of lidocaine as its hydrochloride salt administered subcutaneously (6 horses).	10 ng/mL as 3-hydroxylidocaine in urine; 0.02 ng/mL as 3-hydroxylidocaine in serum or plasma.
BANNED	S0		Lidoflazine	Vasodilator	Lacks FDA approval.		
BANNED	S4		Ligandrol (LGD–4033)	Selective Androgen Receptor Modulator (SARM).	Lacks FDA approval.		
BANNED	S0		Lisinopril	Antihypertensive	Zestoretic, Qbrelis.		
BANNED	S0		Lithium	Mood Stabilizer	Lithobid.		
BANNED	S0	(x)	Lobeline	Respiratory Stimulant	Plant alkaloid (Lobelia, Indian Tobacco) Environmental substance. Lacks FDA approval.		2 ng/mL in serum or plasma.
BANNED	S0		Lofentanil	Opioid Analgesic	Lacks FDA approval.		
BANNED	S0		Lofepramine	Antidepressant	Lacks FDA approval.		
BANNED	S0		Loflazepate, Ethyl	Anxiolytic	Lacks FDA approval.		
BANNED	S2		Lonapegsomatropin	Growth Hormone	FDA Orphan Drug.		
CONTROLLED	S7	B	Loperamide	Anti-diarrheal	Imodium.		
BANNED	S0		Loprazolam	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
CONTROLLED	S7	C	Loratidine	Antihistamine	Claritin.		
BANNED	S0		Lorazepam	Anxiolytic	Ativan. DEA Schedule IV.		
BANNED	S0		Lormetazepam	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Lornoxicam	NSAID	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Losartan	Antihypertensive	Cozaar, Hyzaar [with hydrochlorothiazide].		
BANNED	S0		Loxapine	Antipsychotic	Adasuve.		
BANNED	S3		Lubabegron	Beta adrenergic modulator	Experior.		
BANNED	S0		Lumiracoxib	NSAID	Lacks FDA approval.		
BANNED	S2		Luspatercept	Erythropoiesis	FDA Orphan Drug.		
CONTROLLED—fillies and mares.	S7	B	Luteinizing Hormone (LH)	Reproductive hormone modulator.			

BANNED—intact males and geldings.	S2		Luteinizing Hormone (LH)	Reproductive hormone modulator.			
BANNED	S3		Mabuterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
BANNED	S2		Macimorelin	Growth Hormone	Macrilen.		
CONTROLLED	S7	B	Magnesium sulfate	Sedative/Laxative	Generic.		
BANNED	S0		Maprotiline	Antidepressant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Maprotiline	Antidepressant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Mazindol	Stimulant	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
BANNED	S0		Mebanazine	Antidepressant	Lacks FDA approval.		
BANNED	S0		Mebeverine	Antispasmodic	Lacks FDA approval.		
BANNED	S0		Mebhyroline (Mebhydrolin)	Antihistamine	Lacks FDA approval.		
BANNED	S0		Mebutamate	Sedative/Anxiolytic	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
BANNED	S0		Mecamylamine	Vasodilator	Generic.		
BANNED	S2		Mechano Growth Factors (MGFs).	Growth Hormone.			
BANNED	S0		Meclizine	Antihistamine	Antivert.		
CONTROLLED	S7	B	Meclofenamic acid	NSAID	Discontinued, no FDA-approved product commercially available. Routinely compounded.		
BANNED	S1		Meclofenoxate	Cholinergic nootropic	Lacks FDA approval.		
BANNED	S0	(x)	Meconine	Opioid	Lacks FDA approval.		
BANNED	S0		Medazepam	Sedative/Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
CONTROLLED	S7	B	Medetomidine	Sedative/Analgesic	Domitor, Placadine		5 ng/mL as 3-hydroxydetomidine in urine.
CONTROLLED	S7	B	Medroxyprogesterone	Reproductive hormone	Depo-Provera.		
BANNED	S0		Medrylamine	Antihistamine	Lacks FDA approval.		
BANNED	S0		Medrysone	Corticosteroid	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Mefenamic acid	NSAID	Ponstel.		
BANNED	S0		Mefenorex	Stimulant	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Mefexamide	Stimulant	Lacks FDA approval.		
BANNED	S0		Mefruside	Diuretic	Lacks FDA approval.		
BANNED	S2		Meldonium	Anti-ischemic	Lacks FDA approval.		
CONTROLLED	S7	B	Meloxicam	NSAID	Metacam.		
BANNED	S0		Melperone	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Memantine	Alzheimer's treatment	Namenda; Namzaric (with donepezil).		
BANNED	S0		Meparfynol (methylpentynol)	Sedative	Lacks FDA approval.		
BANNED	S0		Mepazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Mepednisone	Corticosteroid	Lacks FDA approval.		
BANNED	S0		Mepenzolate	Anti-ulcer	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Meperidine	Opioid analgesic	Demerol. DEA Schedule II.		
BANNED	S0		Mephenesin	Muscle relaxant	Lacks FDA approval.		
BANNED	S0		Mephenoxalone	Muscle relaxant	Lacks FDA approval.		
BANNED	S0		Mephentermine	Cardiac stimulant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Mephenytoin	Anticonvulsant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Mephobarbital (Methylphenobarbital).	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Mepindolol	Beta blocker	Lacks FDA approval.		
CONTROLLED	S7	B	Mepivacaine	Local anesthetic	Carbocaine, Polocaine, Scandonest.	Detection Time: 72 hrs. 40 mg (2 ml) single dose SQ distal limb (6 horses).	10 ng/mL as 3-hydroxymepivacaine in urine; 0.05 ng/mL in serum or plasma.

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BANNED	S0		Meprobamate (Meprobamate is a metabolite of carisoprodol. If there is credible evidence that the presence of meprobamate in a horse's sample is the consequence of carisoprodol administration, the classification of meprobamate may be revised to S7(A).).	Anxiolytic	Generic. DEA Schedule IV.		
BANNED	S0		Meprylcaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Meptazinol	Narcotic	Lacks FDA approval.		
BANNED	S5		Meralluride	Diuretic	Lacks FDA approval.		
BANNED	S5		Merbaphen	Diuretic	Lacks FDA approval.		
BANNED	S5		Mercaptomerin	Diuretic	Lacks FDA approval.		
BANNED	S0		Mersalyl	Diuretic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	C	Mesalamine (mesalazine)	Anti-inflammatory	Delzicol, Pentasa,Sfrowasa, Canasa, Lialda.		
BANNED	S0		Mesocarb	Stimulant	Lacks FDA approval.		
BANNED	S0		Mesoridazine	Antipsychotic	Discontinued, no FDA-approved product commercially available.		
BANNED	S1		Mestanolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Mesterolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Metaclazepam	Anxiolytic	Lacks FDA approval.		
BANNED	S1		Metandienone	Anabolic	Lacks FDA approval.		
BANNED	S3		Metaproterenol (Orciprenaline)	Beta-2 agonist-bronchodilator	Generic.		
BANNED	S0		Metaraminol	Anti-hypotensive	Generic.		
BANNED	S0		Metaxalone	Muscle relaxant	Skelaxin.		
BANNED	S0		Metazocine	Opioid analgesic	Lacks FDA approval. DEA Schedule II.		
BANNED	S1		Metenolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Metformin	Anti-hyperglycemic	Fortamet, Glumetza, Glucophage.		
BANNED	S0		Methacholine	Bronchoconstrictor	Provocholine.		
BANNED	S0		Methadone	Synthetic opioid agonist	Methadose. DEA Schedule II.		
BANNED	S0		Methallenestril	Synthetic estrogen	Lacks FDA approval.		
BANNED	S0		Methamphetamine	Stimulant	Desoxyn. DEA Schedule II.		
BANNED	S1		Methandienone	Anabolic steroid	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Methandriol (Methylandrostenediol).	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Methandrostenolone	Anabolic	Lacks FDA approval.		
BANNED	S0		Methantheline	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Methapyrilene	Antihistamine	Lacks FDA approval.		
BANNED	S0		Methaqualone	Sedative	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Metharbital	Sedative	Discontinued, no FDA-approved product commercially available.		
BANNED	S1		Methasterone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Methazolamide	Carbonic Anhydrase Inhibitor	Generic.		
BANNED	S0		Methcathinone	Stimulant	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Methdilazine	Antihistamine	Discontinued, no FDA-approved product commercially available.		

BANNED	S1		Methenolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Methimazole	Anti-thyroid	Generic.		
BANNED	S0		Methixene	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	C	Methocarbamol	Muscle relaxant	Robaxin	Detection Time: 48 hours. 15 mg/kg single IV dose. (20 horses).	1 ng/mL in serum or plasma.
BANNED	S0		Methohexital	Sedative	Brevital.		
CONTROLLED	S7	B	Methotrexate	Immunomodulator	Otrexup, Rasuvo, Reditrex, Trexall.		
BANNED	S0		Methotrimeprazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Methoxamine	Stimulant	Discontinued, no FDA-approved product commercially available.		
BANNED	S3		Methoxyphenamine	Bronchodilator	Lacks FDA approval.		
BANNED	S2		Methoxypolyethylene glycol-epoetin beta (CERA).	Erythropoiesis	Micera.		
BANNED	S0		Methoxytyramine (3-)	Neuromodulator	Endogenous substance		Threshold: 4 mcg/mL total (free and conjugated) 3-methoxytyra-mine per mL in urine.
BANNED	S0		Methscopolamine (Methyl scopolamine).	Anticholinergic	Generic.		
BANNED	S0		Methsuximide	Anticonvulsant	Celontin.		
BANNED	S1		Methyl-1-testosterone	Anabolic	Android 25. DEA Schedule III.		
BANNED	S0		Methylaminorex	Stimulant	Lacks FDA approval. DEA schedule I.		
BANNED	S0		Methylatropine	Anticholinergic	Lacks FDA approval.		
BANNED	S0		Methylchlorthiazide (Methylclothiazide).	Diuretic	Lacks FDA approval.		
BANNED	S1		Methylclostebol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S5		Methylclothiazide	Diuretic	Discontinued, no FDA-approved product commercially available.		
BANNED	S1		Methyldienolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Methyldopa	Antihypertensive	Generic.		
BANNED	S0		Methylenedioxyamphetamine (MDA).	Stimulant	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Methylenedioxyethylamphetamine (MDEA).	Stimulant	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Methylenedioxymethamphetamine (MDMA).	Stimulant	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Methylephedrine	Stimulant	Lacks FDA approval.		
CONTROLLED	S7	C	Methylergonovine	Ergot alkaloid	Methergine.		
BANNED	S0		Methylhexanamine (Methylhexaneamine).	Stimulant	Lacks FDA approval.		
BANNED	S0		Methylmethcathinone	Stimulant	Lacks FDA approval.		
BANNED	S1		Methylnortestosterone (Trestolone).	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Methylphenidate	Stimulant	Ritalin. DEA Schedule II.		
CONTROLLED	S7	C	Methylprednisolone	Corticosteroid	Depo-Medrol.		
BANNED	S0		Methylprylone (methprylon)	Sedative	Lacks FDA approval.		
BANNED	S0		Methylpseudoephedrine	Stimulant	Lacks FDA approval.		
CONTROLLED	S7	C	Methylsalicylate	NSAID	Salonpas (with menthol).		
CONTROLLED	S7	C	Methylsulfonylmethane (MSM)	Anti-inflammatory	Feed contaminant per IFHA		1200 mcg/mL in urine.
BANNED	S1		Methyltestosterone	Anabolic	Android 25. DEA Schedule III.		
BANNED	S1		Methyltrienolone (metribolone)	Anabolic	Lacks FDA approval. DEA Schedule III.F896.		
BANNED	S0		Methyprylon	Sedative	Discontinued, no FDA-approved product commercially available. DEA Schedule III.		
BANNED	S0		Methysergide	Ergot alkaloid	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Metiamide	Antihistamine	Lacks FDA approval.		
BANNED	S5		Meticrane	Diuretic	Lacks FDA approval.		
BANNED	S0		Metipranolol	Antihypertensive	Lacks FDA approval.		

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CONTROLLED	S7	C	Metoclopramide	Anti-emetic/Prokinetic	Gimoti, Reglan.		
BANNED	S0		Metocurine	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
BANNED	S5		Metolazone	Diuretic	Generic.		
BANNED	S0		Metomidate	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S0		Metopon (methydihydromorphinone).	Opioid analgesic	Lacks FDA approval. DEA Schedule II.		
BANNED	S0		Metoprolol	Antihypertensive	Lopressor.		
BANNED	S0		Metrenperone	Myositis preventative	Lacks FDA approval.		
BANNED	S1		Metribolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Metyrapone	Hydrocortisone synthesis inhibitor.	Metopirone.		
BANNED	S0		Mexazolam	Anxiolytic	Lacks FDA approval.		
CONTROLLED	S7	B	Mexiletine	Antiarrhythmic	Generic.		
BANNED	S0		Mianserin	Antidepressant	Lacks FDA approval.		
BANNED	S0		Mibefradil	Antihypertensive	Lacks FDA approval.		
BANNED	S1		Mibolerone	Anabolic	Cheque Drops. DEA Schedule III.		
CONTROLLED	S7	B	Midazolam	Anticonvulsant	Seizalam. DEA Schedule IV.		
BANNED	S0		Midodrine	Antiphyptensive	Orvaten.		
CONTROLLED	S7	B	Milrinone	Vasodilator	Generic.		
BANNED	S0		Minoxidil	Antihypertensive	Rogaine.		
BANNED	S0		Mirtazapine	Antidepressant	Remeron.		
CONTROLLED	S7	C	Misoprostol	Prostaglandin analog	Cytotec	Detection Time: 48 hrs. 5 mcg/kg orally twice daily for 14 days. (6 horses).	
BANNED	S0		Mitragynine	Stimulant	Lacks FDA approval.		
BANNED	S0		Mivacurium	Muscle relaxant	Generic.		
BANNED	S0		Modafinil	Stimulant	Provigil. DEA Schedule IV.		
BANNED	S0		Moexipril (metabolite, moexiprilat).	Antihypertensive	Generic.		
BANNED	S0		Mofebutazone	NSAID	Lacks FDA approval.		
BANNED	S2		Molidustat (BAY 85–3934)	Erythropoiesis	Lacks FDA approval.		
BANNED	S0		Molindone	Antipsychotic	Generic.		
CONTROLLED	S7	C	Mometasone	Corticosteroid	Asmanex, Sinuva, Elocon, Ryaltris, Nasonex.		
CONTROLLED	S7	C	Montelukast	Leukotriene receptor antagonist	Singulair.		
BANNED	S0		Moperone	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Moprolol	Antihypertensive	Lacks FDA approval.		
BANNED	S0		Morpheridine	Analgesic	Lacks FDA approval.		
CONTROLLED	S7	A (x)	Morphine	Opioid Analgesic	Duramorph, Infumorph, Mitigo, MS Contin. DEA Schedule II; Dietary substance per IFHA.		30 ng/mL total (free and conjugated) in urine.
BANNED	S0		Mosapramine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Moxaverine	Vasodilator	Lacks FDA approval.		
BANNED	S0	(x)	Muscarine	Cholinergic	Plant alkaloid.		
BANNED	S0		Myo-inositol trispyrophosphate (ITPP, OXY111A).	Oxygen transfer	Lacks FDA approval.		
CONTROLLED	S7	B	Nabumetone	NSAID	Generic.		
BANNED	S0		Nadolol	Antihypertensive	Corgard.		
BANNED	S0		Nadoxolol	Antihypertensive	Lacks FDA approval.		
BANNED	S0		Naepaine	Local anesthetic	Lacks FDA approval.		
BANNED	S2		Nafarelin	Reproductive hormone modulator.	Synarel.		
BANNED	S0		Naftidrofuryl	Vasodilator	Lacks FDA approval.		
BANNED	S0		Nalbuphine	Opioid receptor agonist and antagonist.	Generic.		
CONTROLLED	S7	A	Nalmefene	Opioid antagonist	Revex.		

BANNED	S0		Nalorphine	Opioid receptor agonist and antagonist.	Nalline. DEA Schedule III.F943.		
CONTROLLED	S7	B	Naloxone	Opioid antagonist	Narcan, Zimhi, Suboxone (with buprenorphine hydrochloride), Zubsolv (with buprenorphine hydrochloride).		
CONTROLLED	S7	A	Naltrexone	Opioid antagonist	Trexonil.		
BANNED-fillies, mares and geldings.	S1		Nandrolone (19-nortestosterone)	Anabolic	Discontinued, no FDA-approved product commercially available. DEA schedule III.		
CONTROLLED	S7	B	Naphazoline	Sympathomimetic	Naphcon-A (with pheniramine maleate), Opcon-A (with pheniramine maleate), Visine (with pheniramine maleate).		
CONTROLLED	S7	C	Naproxen	NSAID	Aleve, Naprosyn, Anaprox.		
BANNED	S0		Naratriptan	Selective Serotonin Receptor Agonist.	Amerge.		
CONTROLLED	S7	C	N-Butylscopolammonium	Anti-cholinergic	Buscopan	Detection Time: 48 hrs. 0.3 mg/kg single IV dose (6 horses).	25 ng/mL in urine.
BANNED	S0		Nebivolol	Antihypertensive	Bystolic.		
CONTROLLED	S7	C	Nedocromil	Mast Cell Stabilizer	Alocril.		
BANNED	S0		Nefazodone	Antidepressant	Generic.		
BANNED	S0		Nefopam	Analgesic	Lacks FDA approval.		
CONTROLLED	S7	B	Neostigmine	Anticholinesterase	Bloxiverz.		
BANNED	S6		Neridronate	Bisphosphonate	Lacks FDA approval.		
BANNED	S0		Nialamide	Antidepressant	Lacks FDA approval.		
BANNED	S0		Nicardipine	Antihypertensive	Generic.		
BANNED	S0		Nicoumalone	Anticoagulant	Lacks FDA approval.		
BANNED	S0		Nifedipine	Antihypertensive	Procardia.		
BANNED	S0		Nifenalol	Antihypertensive/Antiarrhythmic	Lacks FDA approval.		
BANNED	S0		Niflumic acid	NSAID	Lacks FDA approval.		
BANNED	S0		Nikethamide	Stimulant	Lacks FDA approval.		
BANNED	S0		Nimesulide	NSAID	Lacks FDA approval.		
BANNED	S0		Nimetazepam	Hypnotic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Nimodipine	Calcium channel blocker	Generic.		
BANNED	S0		Nitrazepam	Sedative/Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Nitroglycerin	Vasodilator	Nitromist, Nitro-Dur, Nitrostat.		
CONTROLLED	S7	C	Nizatidine	Anti-ulcer	Axid.		
BANNED	S0		Nomifensine	Antidepressant	Lacks FDA approval.		
BANNED	S1		Norandrostenediol	Anabolic	Lacks FDA approval.		
BANNED	S1		Norandrostenedione	Anabolic	Lacks FDA approval.		
BANNED	S1		Norandrosterone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Norbolethone/Norboletone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Norclostebol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Nordiazepam/Nordazepam (Nordiazepam is a metabolite of diazepam. If there is credible evidence that the presence of nordiazepam in a horse's sample is the consequence of exposure to diazepam, the classification of nordiazepam may be revised to S7(A).).	Sedative/Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
CONTROLLED	S7	A	Norepinephrine	Stimulant	Levophed.		
BANNED	S1		Norethandrolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Norethisterone (norethindrone)	Anabolic	Combipatch, Activella, Amabelz, Nortrel, Alyacen, Aranelle and multiple others (with estradiol).		

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit*
BANNED	S0		Norfenefrine	Antihypotensive	Lacks FDA approval.		
BANNED	S0		Norfenfluramine	Stimulant	Lacks FDA approval.		
BANNED	S0		Norfluoxetine (Seproxetine)	Antidepressant	Lacks FDA approval.		
BANNED	S0		Norpseudoephedrine (cathine)	Stimulant	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Nortriptyline	Antidepressant	Pamelor.		
BANNED	S0		Noscapine	Antitussive	Lacks FDA approval.		
BANNED	S0		Nylidrin (buphenine)	Vasodilator	Lacks FDA approval.		
BANNED	S0		Octopamine (Octopamine is a metabolite of ephedrine. If there is credible evidence that the presence of octopamine is a consequence of exposure to ephedrine, the classification of octopamine may be revised to S7(A).).	Stimulant	Lacks FDC approval.		
BANNED	S0		Olanzapine	Antipsychotic	Zyprexa.		
BANNED	S0		Oliceridine	Opioid agonist	Olinvk. DEA Schedule II.		
BANNED	S0		Olmesartan	Antihypertensive	Benicar (with medoxomil).		
BANNED	S3		Olodaterol	Beta-2 agonist-bronchodilator	Striverdi Respimat, Stiolto Respimat (with tiotropium bromide).		
BANNED	S6		Olpadronate	Bisphosphonate	Lacks FDA approval.		
CONTROLLED	S7	C	Olsalazine	Anti-inflammatory	Diipentum.		
CONTROLLED	S7	C	Omeprazole	Anti-ulcer	Gastrogard	Restricted administration time: 24 hours. 2.2 g orally once daily for 4 doses (9 horses).	10 ng/mL in serum or plasma as omeprazole sulfide.
BANNED	S0		Opipramol	Antidepressant	Lacks FDA approval.		
CONTROLLED	S3		Orciprenaline (Metaproterenol)	Beta-2 agonist-bronchodilator	Generic.		
BANNED	S0	(x)	Oripavine	Opioid	Plant alkaloid. DEA schedule II.		
BANNED	S0		Orphenadrine	Muscle relaxant	Generic.		
BANNED	S4		Ospemifene	Selective Estrogen Receptor Modulator (SERM).	Osphena.		
BANNED	S1		Ostarine (enobosarm)	Selective Androgen Receptor Modulator (SARM).	Lacks FDA approval.		
BANNED	S1		Oxabolone	Anabolic	Lacks FDA approval.		
BANNED	S0		Oxaflumazine	Psychosedative	Lacks FDA approval.		
BANNED	S1		Oxandrolone	Anabolic	Generic. DEA Schedule III.		
BANNED	S0		Oxaprozin	NSAID	Daypro.		
BANNED	S0		Oxazepam (Oxazepam is a metabolite of diazepam. If there is credible evidence that the presence of oxazepam in a horse's sample is the consequence of exposure to diazepam, the classification of oxazepam may be revised to S7(A).).	Anxiolytic	Generic. DEA Schedule IV.		
BANNED	S0		Oxazolam	Sedative/Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Oxcarbazepine	Anticonvulsant	Generic.		
BANNED	S0		Oxethazaine (Oxetacaine)	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Oxilofrine (hydroxyephedrine)	Stimulant	Lacks FDA approval.		
BANNED	S0		Oxolamine	Antitussive	Lacks FDA approval.		
BANNED	S0		Oxprenolol	Antihypertensive	Lacks FDA approval.		
CONTROLLED	S7	C	Oxybuprocaine (Benoxinate, oxybucaine).	Local anesthetic	Atafluor Benox.		

BANNED	S0		Oxycodone	Opioid Analgesic	Oxycontin, Roxybond, Roxicodone, Oxaydo, Xtampza; Percocet, Percodan, Oxycet (with NSAID). DEA Schedule II.
BANNED	S1		Oxyguno	Anabolic	Lacks FDA approval.
BANNED	S1		Oxymesterone	Anabolic	Lacks FDA approval. DEA Schedule III.
CONTROLLED	S7	B	Oxymetazoline	Nasal decongestant	Rhofade, Upneq, Visine.
BANNED	S1		Oxymetholone	Anabolic	Discontinued, no FDA-approved product commercially available. DEA Schedule III.
BANNED	S0		Oxymorphone	Opioid analgesic	Generic. DEA Schedule II.
BANNED	S0		Oxypertine	Antipsychotic	Lacks FDA approval.
BANNED	S0		Oxyphencyclimine	Anticholinergic	Discontinued, no FDA-approved product commercially available.
BANNED	S0		Oxyphenonium	Anticholinergic	Discontinued, no FDA-approved product commercially available.
CONTROLLED	S7	B	Oxytocin	Uterine contraction	Pitocin.
BANNED	S0		Paliperidone	Antipsychotic	Invega.
BANNED	S0		Palmitoylethanolamid	Anti-inflammatory	Lacks FDA approval.
BANNED	S6		Pamidronate	Bisphosphonate	Generic.
CONTROLLED	S7	A	Pancuronium	Muscle relaxant	Generic.
CONTROLLED	S7	C	Pantoprazole	Anti-ulcer	Protonix.
BANNED	S0	(x)	Papaverine	Vasodilator	Plant alkaloid.
BANNED	S0		Paraldehyde	Anticonvulsant	Lacks FDA approval. DEA Schedule IV.
BANNED	S0		Paramethadione	Anticonvulsant	Discontinued, no FDA-approved product commercially available.
BANNED	S0		Paramethasone	Corticosteroid	Discontinued, no FDA-approved product commercially available.
BANNED	S0	(x)	Paraxanthine (Paraxanthine is a metabolite of caffeine. If there is credible evidence that the presence of paraxanthine in a horse's sample is the consequence of exposure to caffeine, the classification of paraxanthine may be revised to S7(B).).	Stimulant	Lacks FDA approval.
BANNED	S0		Parecoxib	NSAID	Lacks FDA approval.
BANNED	S0		Pargyline	Antihypertensive	Discontinued, no FDA-approved product commercially available.
BANNED	S0		Paroxetine	Antidepressant	Paxil.
BANNED	S2		Pegepoietin	Erythropoiesis	Micera.
BANNED	S2		Peginesatide	Erythropoiesis	Discontinued, no FDA-approved product commercially available.
BANNED	S0		Pemoline	Stimulant	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.
BANNED	S0		Pempidine	Ganglion blocker/ antihypertensive.	Lacks FDA approval.
BANNED	S0		Penbutolol	Antihypertensive	Discontinued, no FDA-approved product commercially available.
BANNED	S0		Penfluridol	Antipsychotic	Lacks FDA approval.
BANNED	S0		Pentaerythritol tetranitrate	Vasodilator	Lacks FDA approval.
CONTROLLED	S7	B	Pentazocine	Opiate analgesic	Generic (with naloxone hydrochloride). DEA Schedule IV.
BANNED	S0		Pentetrazol	Stimulant	Lacks FDA approval.
BANNED	S0		Pentifylline	Vasodilator	Lacks FDA approval.
CONTROLLED	S7	A	Pentobarbital	Barbiturate	Nembutal. DEA Schedule II.
CONTROLLED	S7	C	Pentoxyfylline	Vasodilator	Discontinued, no FDA-approved product commercially available.
BANNED	S0		Pentylenetetrazol	Stimulant	Lacks FDA approval.
BANNED	S2		Perfluorodecahydronophthalene	Oxygen transfer	Lacks FDA approval.
BANNED	S0		Perfluorodecalin (Octadecafluoronaphthalene).	Oxygen transport	Lacks FDA approval.

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BANNED	S2		Perfluorooctyl bromide	Oxygen transfer	Discontinued, no FDA-approved product commercially available.		
BANNED	S2		Perfluorotripropylamine	Oxygen transfer	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	B	Pergolide	Dopamine agonist	Prascend.		
BANNED	S0		Periciazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Perindopril	Antihypertensive	Generic, Prestalia (with amlodipine besylate).		
BANNED	S0		Perlapine	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S0		Perphenazine	Antipsychotic	Generic.		
BANNED	S0		Phenacemide	Anticonvulsant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Phenaglycodol	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Phenazocine	Opioid analgesic	Lacks FDA approval. DEA Schedule II.		
BANNED	S0		Phenazone	NSAID	Lacks FDA approval.		
CONTROLLED	S7	A	Phenazopyridine	Local anesthetic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Phencyclidine (PCP)	Dissociative hallucinogen	Lacks FDA approval. DEA Schedule I.		
BANNED	S0		Phendimetrazine	Stimulant	Bontril. DEA Schedule III.		
BANNED	S0		Phenelzine	Antidepressant	Nardil.		
BANNED	S0		Phenibut	Anxiolytic	Lacks FDA approval.		
BANNED	S0		Phenindamine	Antihistamine	Lacks FDA approval.		
BANNED	S0		Phenindione	Anticoagulant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Pheniramine	Antihistamine	Bromfed-DM (with dextromethorphan and pseudoephedrine).		
BANNED	S0		Phenmetrazine	Stimulant	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	A	Phenobarbital	Barbiturate	predates FDA, grandfathered. DEA schedule IV.		
BANNED	S0		Phenoxybenzamine	Antihypertensive	Dibenzyline.		
BANNED	S0		Phenprocoumon	Anticoagulant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Phenpromethamine	Stimulant	Lacks FDA approval.		
BANNED	S0		Phensuximide	Anticonvulsant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Phentermine	Stimulant	Adipex-P, Lomaira, Qsymia. DEA Schedule IV.		
CONTROLLED	S7	B	Phentolamine	Vasodilator	Oraverse.		
CONTROLLED	S7	C	Phenylbutazone	NSAID (3 NSAIDs (Flunixin, Ketoprofen, Phenylbutazone) are associated with a Detection Time of 48 hours. Only one of the three may be administered using a Withdrawal Interval based on the 48 hour Detection Time. To avoid a stacking violation (detection of more than 1 NSAID in a blood sample) the following secondary Detection Times should be applied for the following NSAIDs: Flunixin: 144 hours; Ketoprofen: 96 hours; Phenylbutazone: 168 hours.).	Butazolidin, Butatron, EquiBute, Phen Buta Vet, Bizolin, Butequine, Superiorbute, Pributazone.	Detection Time: 48 hours. 4.4 mg/kg single IV dose. (17 horses).	0.2 mcg/mL in serum or plasma. *Note:* The detection of more than one NSAID in a horse's post-Race or post-Official Workout blood and sample constitutes a Stacking Violation.
CONTROLLED	S7	B	Phenylephrine	Stimulant	Biorphen.		

BANNED	S0		Phenylpiracetam (Carphedon)	Stimulant	Lacks FDA approval.		
BANNED	S0		Phenylpropanolamine	Stimulant	Proin.		
BANNED	S0		Phenyltoloxamine	Antihistamine	Lacks FDA approval.		
CONTROLLED	S7	B	Phenytoin	Anti-convulsant	Dilantin, Phenytek.		
BANNED	S0		Pholcodine	Opioid antitussive	Lacks FDA approval; DEA Schedule I.		
BANNED	S0		Pholedrine	Stimulant	Lacks FDA approval.		
CONTROLLED	S7	A	Physostigmine	Acetylcholinesterase inhibitor	Antilirium.		
BANNED	S0		Picrotoxin	Stimulant	Lacks FDA approval.		
BANNED	S0		Piminodine	Opioid analgesic	Lacks FDA approval. DEA Schedule II.		
BANNED	S1		Pimobendan	Cardiac stimulant	Vetmedin.		
BANNED	S0		Pimozide	Antipsychotic	Generic.		
BANNED	S0		Pinazepam	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S0		Pinazepam	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Pindolol	Antihypertensive	Generic.		
BANNED	S0		Pipamazine	Anti-emetic	Lacks FDA approval.		
BANNED	S0		Pipamperone	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Pipecuronium	Muscle relaxant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Pipequaline	Anxiolytic	Lacks FDA approval.		
BANNED	S0		Piper Methysticum (kava)	Anxiolytic/Anti-inflammatory	Lacks FDA approval.		
BANNED	S0		Piperacetazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Piperidione	Sedative	Lacks FDA approval.		
BANNED	S0		Piperidolate	Antispasmodic	Lacks FDA approval.		
BANNED	S0		Piperocaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Piperoxan	Antihistamine/Antihypertensive	Lacks FDA approval.		
BANNED	S0		Pipotiazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Pipradrol	Stimulant	Lacks FDA approval.		
BANNED	S0		Piquindone	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Piracetam	Stimulant	Lacks FDA approval.		
BANNED	S0		Pirbuterol	Beta-2 agonist-bronchodilator	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Pirenzepine	Anticholinergic	Lacks FDA approval.		
BANNED	S5		Piretanide	Diuretic	Lacks FDA approval.		
BANNED	S0		Piritramide	Synthetic opioid analgesic	Lacks FDA approval.		
CONTROLLED	S7	B	Piroxicam	NSAID	Feldene.		
BANNED	S0		Pirprofen	NSAID	Lacks FDA approval.		
BANNED	S6		Pitcher Plant Extract	Analgesic	Sarapin.		
BANNED	S0		Pizotifen (Pizotylline)	Antimigraine	Lacks FDA approval.		
BANNED	S2		Platelet-Derived Growth Factor (PDGF).	Growth Hormone.			
BANNED	S5		Polythiazide	Diuretic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	A	Potassium Bromide	Anti-convulsant/anxiolytic	KBroVet-CA1.		
BANNED	S0		Practolol	Antiarrhythmic	Lacks FDA approval.		
BANNED	S2		Pralmorelin	Growth Hormone	Lacks FDA approval.		
CONTROLLED	S7	C	Pramoxine	Topical anesthetic	Epifoam (with hydrocortisone acetate), Pramosone (with hydrocortisone acetate).		
BANNED	S1		Prasterone (dehydroepiandrosterone, DHEA, 3βhydroxyandrost-5-en17-one).	Anabolic	Intrarosa.		
BANNED	S0		Prazepam	Sedative/Anxiolytic	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
BANNED	S0		Prazosin	Antihypertensive	Minipress.		
CONTROLLED	S7	C	Prednisolone	Corticosteroid	Endogenous subtance (urine only) per IFHA.		Threshold: 0.01 mcg/mL free prednisolone in urine.
CONTROLLED	S7	C	Prednisone	Corticosteroid	Rayos.		
CONTROLLED	S7	A	Pregabalin	Anticonvulsant/Analgesic	Lyrica. DEA Schedule V.		
BANNED	S0		Prenylamine	Vasodilator	Lacks FDA approval.		
BANNED	S0		Pridinol	Anticholinergic	Lacks FDA approval.		

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BANNED	S0		Prifinium Bromide	Antispasmodic	Lacks FDA approval.		
CONTROLLED	S7	B	Prilocaine	Local	Emla (with lidocaine), Oraqix (with lidocaine), Citanest (with epinephrine).		
CONTROLLED	S7	B	Primidone	Anticonvulsant	Mysoline.		
BANNED	S5		Probenecid	Anti-gout	Probalan.		
CONTROLLED	S7	B	Procainamide	Antiarrhythmic	Generic.		
CONTROLLED	S7	B	Procaine	Local anesthetic	(with Penicillin G)	17 mg (~17,000 IU) per kg IM.	25 ng/mL in serum or plasma.
BANNED	S0		Procarbazine	Antineoplastic	Matulane.		
BANNED	S3		Procaterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
BANNED	S0		Prochlorperazine	Anti-nausea	Compro, Procomp, Compazine.		
BANNED	S0		Procyclidine	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Proglumide	Anti-ulcer	Lacks FDA approval.		
CONTROLLED	S7	B	Promazine	Sedative/Antipsychotic	Promazine Granules.		
CONTROLLED	S7	B	Promethazine	Antihistamine	Promethegan. *Note:* Component of multiple OTC cough/cold formulations.		
BANNED	S0		Pronethalol	Antiarrhythmic	Lacks FDA approval.		
CONTROLLED	S7	B	Propafenone	Antiarrhythmic	Rythmol.		
BANNED	S0		Propallylonal	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S0		Propanidid	Anesthetic	Lacks FDA approval.		
BANNED	S0		Propantheline	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	C	Proparacaine (Proxymetacaine)	Local anesthetic	Alcane.		
BANNED	S0		Propentophylline (propentofylline).	Phosphodiesterase inhibitor	Lacks FDA approval.		
BANNED	S0		Propiomazine	Antipsychotic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Propionylpromazine	Sedative	Lacks FDA approval.		
BANNED	S0		Propiram	Opioid analgesic	Lacks FDA approval. DEA Schedule I.		
CONTROLLED	S7	A	Propofol	Anesthetic	PropoFlo, Rapanofal.		
BANNED	S0		Propoxycaine	Local anesthetic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Propoxyphene	Opioid analgesic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	A	Propranolol	Antiarrhythmic/Antihypertensive	Inderal, Hemangeol.		
BANNED	S0		Propylhexedrine	Stimulant	Benzedrex.		
BANNED	S0		Propyphenazone	NSAID	Lacks FDA approval.		
BANNED	S0		Proquazone	NSAID	Lacks FDA approval.		
BANNED	S1		Prostanazol	Anabolic	Lacks FDA approval. DEA Schedule III.F1166.		
BANNED	S0		Prothipendyl	Anxiolytic/Antihistamine	Lacks FDA approval.		
BANNED	S0		Protokylol	Bronchodilator	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Protriptyline	Antidepressant	Generic.		
BANNED	S0		Proxibarbital	Sedative/Anxiolytic	Lacks FDA approval.		
BANNED	S0		Proxyphylline	Bronchodilator	Lacks FDA approval.		
CONTROLLED	S7	B	Pseudoephedrine	Stimulant	Sudafed.		
BANNED	S0		Psilocin (Psilocyn)	Hallucinogen	Lacks FDA approval; DEA Schedule I.		
CONTROLLED	S7	B	Pyridostigmine	Cholinesterase Inhibitor	Mestinon, Regonol.		
CONTROLLED	S7	B	Pyrilamine	Antihistamine	Histavet-P.		
BANNED	S0		Pyrithyldione	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S0		Pyrrobutamine	Antihistamine	Lacks FDA approval.		
BANNED	S0		Quazepam	Sedative	Doral.DEA Schedule IV.		
BANNED	S0		Quetiapine	Antipsychotic	Lacks FDA approval.		

BANNED	S0		Quinapril, Quinaprilat	Antihypertensive	Accuretic.		
BANNED	S1		Quinbolone	Anabolic	Lacks FDA approval.		
BANNED	S5		Quinethazone	Diuretic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	B	Quinidine	Anti-arrhythmic	Generic.		
BANNED	S0		Quinisocaine	Local anesthetic	Lacks FDA approval.		
CONTROLLED	S7	C	Rabeprazole	Anti-ulcer	Aciphex.		
BANNED	S0		Racemethorphan	Anti-Alzheimer's	Lacks FDA approval. DEA Schedule II.		
BANNED	S0		Racemorphan	Opioid agonist	Lacks FDA approval. DEA Schedule II.		
BANNED	S0		Raclopride	Antipsychotic	Lacks FDA approval.		
BANNED	S1	(x)	Ractopamine	Anabolic	Paylean, Optaflexx, Topmax.		
BANNED	S4		Raloxifene	Selective Estrogen Receptor Modulator (SERM).	Evista.		
BANNED	S4		Ramatercept (ACE–031)	Myostatin inhibitor	Lacks FDA approval.		
BANNED	S0		Ramifenazone (Isopyrin)	NSAID	Lacks FDA approval.		
BANNED	S0		Ramipril, metabolite Ramiprilat	Antihypertensive	Altace.		
CONTROLLED	S7	C	Ranitidine	Anti-ulcer	Generic	Restricted administration time: 24 hours. 8 mg/kg orally twice daily for 7 doses. (9 horses).	40 ng/mL in serum or plasma.
BANNED	S0		Regadenoson	Cardiac stimulant	Lexiscan.		
BANNED	S0		Remifentanil	Synthetic opioid analgesic	Ultiva. DEA Schedule II.		
BANNED	S0		Remimazolam	Anesthetic	Byfavo. DEA schedule IV.		
BANNED	S0		Remoxipride	Antipsychotic	Lacks FDA approval.		
BANNED	S3		Reproterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
CONTROLLED	S7	A	Reserpine	Antihypertensive/Depressant	Serpasil.		
BANNED	S0		Rilmazafone	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S3		Rimiterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
BANNED	S6		Risedronate	Bisphosphonate	Actonel.		
BANNED	S0		Risperidone	Antipsychotic	Perseris Kit, Risperdal Consta, Risperdal.		
BANNED	S0		Ritanserin	Antidepressant	Lacks FDA approval.		
BANNED	S3		Ritodrine	Beta-2 agonist	Lacks FDA approval.		
BANNED	S0		Rivastigmine	Cholinesterase Inhibitor	Exelon.		
BANNED	S0		Rizatriptan	Selective Serotonin Receptor Agonist.	Maxalt.		
CONTROLLED	S7	A	Rocuronium	Muscle relaxant	Generic.		
BANNED	S0		Rofecoxib	NSAID	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	B	Romifidine	Sedative	Sedivet	Detection Time: 60 hours. 80 mcg/kg single IV dose (6 horses).	1 ng/mL in urine.
CONTROLLED	S7	A	Ropivacaine	Local anesthetic	Naropin.		
BANNED	S2		Roxadustat (FG–4592)	Erythropoiesis	Lacks FDA approval.		
BANNED	S0		Salicylamide	Analgesic	Lacks FDA approval.		
CONTROLLED—when administered via inhalation.	S7	B	Salmeterol	Beta-2 agonist-bronchodilator	Serevent, Advair (with fluticasone), Airduo (with fluticasone), Wixela (with fluticasone).		
BANNED	S1		SARM YK–11	Anabolic	Lacks FDA approval.		
CONTROLLED	S7	C (x)	Scopolamine (Hyoscine)	Anticholinergic	Transdermal Scop; Dietary substance per IFHA.		60 ng/mL total (free and conjugated) in urine.
CONTROLLED	S7	A	Secobarbital (Quinalbarbitone)	Sedative/Hypnotic	Discontinued, no FDA-approved product commercially available. DEA Schedule II.		
BANNED	S0		Selegiline	Antidepressant	Emsam, Zelapar.		
BANNED	S2		Sermorelin	Growth Hormone	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Sertraline	Antidepressant	Zoloft.		
BANNED	S0		Sibutramine	Stimulant	Discontinued, no FDA-approved product commercially available. DEA Schedule IV.		
BANNED	S0		Sildenafil	Phosphodiesterase inhibitor	Viagra.		
BANNED	S6		Snake Venoms	Neurotoxin	Lacks FDA approval.		
BANNED	S2		Somatrem	Growth Hormone	Protropin.		

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit*
BANNED	S2		Somatrogon	Growth Hormone	Lacks FDA approval.		
BANNED	S2		Somatropin	Growth Hormone	Lacks FDA approval.		
CONTROLLED	S7	B	Sotalol	Antiarrhythmic	Betapace, Sorine, Sotylize.		
BANNED	S2		Sotatercept	Growth Hormone	Lacks FDA approval.		
BANNED	S0	(x)	Sparteine	Antiarrhythmic	Lacks FDA approval.		
BANNED	S0		Spiperone	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Spirapril, metabolite Spiraprilat	Antihypertensive	Discontinued, no FDA-approved product commercially available.		
BANNED	S5		Spironalactone	Diuretic	Aldactazide, Caarospir, Aldactone.		
BANNED	S4		Stamulumab (Myo-29)	Myostatin inhibitor	Lacks FDA approval.		
BANNED	S1		Stanozolol	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S1		Stenbolone	Anabolic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Strychnine	CNS stimulant	Lacks FDA approval. (Has anetodal use as contituent of unregulated appetite stimulants and leg paints. Extreme caution is advised when using these products.).		
BANNED	S0		Styramate	Muscle relaxant	Lacks FDA approval.		
CONTROLLED	S7	A	Succinylcholine	Muscle relaxant	Anectine, Quelicin.		
BANNED	S0		Sufentanil	Opioid analgesic	Sufenta, Dsuvia. DEA Schedule II.		
CONTROLLED	S7	C	Sulfasalazine	Disease-modifying anti-rheumatic.	Azulfadine.		
BANNED	S0		Sulfondiethylmethane	Sedative/Hypnotic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Sulfonmethane	Sedative/Hypnotic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Sulforidazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Sulindac	NSAID	Generic.		
BANNED	S0		Sulpiride	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Sultopride	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Sumatriptan	Selective Serotonin Receptor Agonist.	Imitrex, Treximet [with naproxen].		
CONTROLLED	S7	C	Suprofen	NSAID	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Suxibuzone	NSAID	Lacks FDA approval.		
BANNED	S0	(x)	Synephrine	Stimulant	Lacks FDA approval.		
BANNED	S4		T3 (triiodothyronine)	Metabolic hormone	Lacks FDA approval.		
BANNED	S4		T4 (tetraiodothyronine/thyroxine).	Metabolic hormone	Thyro-Tabs Canine, Thyrokare.		
BANNED	S2		Tabimorelin	Growth Hormone	Lacks FDA approval.		
BANNED	S0		Tadalafil	Phosphodiesterase inhibitor	Cialis.		
BANNED	S0		Talbutal	CNS depressant	Discontinued, no FDA-approved product commercially available. DEA Schedule III.		
BANNED	S4		Tamoxifen	Selective Estrogen Receptor Modulator (SERM).	Soltamox.		
BANNED	S0		Tandospirone	Anxiolytic	Lacks FDA approval.		
BANNED	S0		Tapentadol	Opioid analgesic	Nucynta. DEA Schedule II.		
BANNED	S0		Telmisartan	Antihypertensive	Micardis.		

CONTROLLED	S7	B	Temazepam (Temazepam is a major metabolite of diazepam. If there is credible evidence that the presence of temazepam in a horse's sample is the consequence of exposure to diazepam, the classification of temazepam may be revised to S7(B).).	Anxiolytic	Restoril. DEA Schedule IV.		
BANNED	S0		Tenoxicam	NSAID	Lacks FDA approval.		
CONTROLLED	S7	B	Tepoxalin	NSAID	Zubrin.		
BANNED	S0		Terazosin	Antihypertensive	Generic.		
BANNED	S3		Terbutaline	Bronchodilator	Brethine.		
BANNED	S0		Terfenadine	Antihistamine	Lacks FDA approval.		
BANNED	S2		Tesamorelin	Growth Hormone	Egrifta.		
BANNED	S4		Testolactone	Aromatase inhibitor	Teslac. DEA Schedule III.		
BANNED	S2		Testolone	Selective Androgen Receptor Modulator (SARM).	Lacks FDA approval.		
BANNED—Fillies and Mares (unless in foal).	S1		Testosterone	Anabolic	Androderm, Testm, Vogelxo, Testopel, Aveed, Kyzatrex, Jatenzo, Xyosted. DEA Schedule III.		Threshold: 55 ng/mL total (free and conjugated) testosterone in urine OR 0.1 n/mL free testosterone in serum or plasma.
BANNED—Geldings	S1		Testosterone	Anabolic	Androderm, Testm, Vogelxo, Testopel, Aveed, Kyzatrex, Jatenzo, Xyosted. DEA Schedule III.		Threshold: 20 ng/mL total (free and conjugated) testosterone in urine OR 0.1 ng/mL free testosterone in serum or plasma.
BANNED	S0		Tetrabenazine (deutetrabenazine).	Neurotransmitter modulator	Xenazine, Austedo.		
CONTROLLED	S7	B	Tetracaine	Local anesthetic	Pliaglis [with lidocaine], Synera [with lidocaine], Kovanze [with oxymetazoline].		
BANNED	S1		Tetrahydrogestrinone	Anabolic	Lacks FDA approval. DEA Schedule III.		
CONTROLLED	S7	B	Tetrahydrozoline	Topical Decongestant	Visine.		
BANNED	S0		Tetrazepam	Anxiolytic	Lacks FDA approval. DEA Schedule IV.		
BANNED	S1		THC (tetrahydrocannabinol)	Psychoactive	Lacks FDA approval. DEA Schedule I.		
BANNED	S0	(x)	Thebaine	Opioid analgesic	Lacks FDA approval. DEA Schedule II.		
CONTROLLED	S7	B (x)	Theobromine	Bronchodilator/Vasodilator	Lacks FDA approval; Dietary substance per IFHA.		Threshold: mcg/mL (free and conjugated) in urine OR 0.3 mcg/mL in serum or plasma.
CONTROLLED	S7	B (x)	Theophylline	Bronchodilator	Generic; Dietary subtance per IFHA.		Threshold: 250 ng/mL (free and conjugated) in urine.
BANNED	S0		Thialbarbital	Sedative/Hypnotic	Lacks FDA approval.		
CONTROLLED	S7	A	Thiamylal	Sedative/Hypnotic	Surital, Biotal, Anestatal. DEA Schedule III.		
BANNED	S0		Thiethylperazine	Antipsychotic	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	A	Thiopental (pentothal)	Anesthetic	Combuthal Powder, Xylamed. DEA Schedule III.		
BANNED	S0		Thiopropazate	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Thioproperazine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Thioridazine	Antipsychotic	Generic.		
BANNED	S0		Thiothixene	Antipsychotic	Generic.		
BANNED	S0		Thiphenamil (tifenamil)	Antispasmodic/Local anesthetic	Lacks FDA approval.		
BANNED	S0		Thonzylamine	Antihistamine/anticholinergic	Lacks FDA approval.		
BANNED	S0		Thozalinone	Antidepressant	Lacks FDA approval.		
BANNED	S2		Thymosin	Peptide hormone	Lacks FDA approval.		

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit*
BANNED	S0		Tiapride	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Tiaprofenic acid	NSAID	Lacks FDA approval.		
BANNED	S1		Tibolone	Anabolic	Lacks FDA approval.		
BANNED	S6		Tildronate (Tiludronic Acid)	Bisphosphonate	Tildren.		
CONTROLLED	S7	A	Tiletamine	Anesthetic	Telazol [with zolazepam]. DEA Schedule III.		
BANNED	S0		Timiperone	Antipsychotic	Lacks FDA approval.		
BANNED	S3		Timolol	Antihypertensive	Istalol, Betimol, Timoptic.		
CONTROLLED	S7	B	Tiotropium	Bronchodilator	Spiriva.		
BANNED	S0		Tocainide	Antiarrhythmic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Tofenacin	Antidepressant	Lacks FDA approval.		
BANNED	S0		Tofisopam	Anxiolytic	Lacks FDA approval.		
CONTROLLED	S7	A	Tolazoline	Vasodilator	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Tolfenamic Acid	NSAID	Lacks FDA approval.		
BANNED	S0		Tolmetin	NSAID	Discontinued, no FDA-approved product commercially available.		
BANNED	S5		Tolvaptan	Diuretic	Jynarque, Samsca.		
BANNED	S0		Tolycaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Topiramate	Anticonvulsant	Topamax, Qsymia (with phentermine hydrochloride).		
BANNED	S4		Toremifene	Selective Estrogen Receptor Modulator (SERM).	Fareston.		
BANNED	S5		Torsemide (Torasemide)	Diuretic	Soaanz.		
CONTROLLED	S7	B	Tramadol	Opioid Analgesic	Ultram. DEA Schedule IV.		
BANNED	S0		Tramazoline	Sympathomimetic	Lacks FDA approval.		
BANNED	S0		Trandolapril (and metabolite, trandolaprilat).	Antihypertensivle	Generic.		
CONTROLLED	S7	C	Tranexamic acid	Antifibrinolytic	Cykokapron.		
BANNED	S0		Tranylcypromine	Antidepressant	Parnate.		
BANNED	S0		Trazodone	Antidepressant	Generic.		
BANNED	S1		Trenbolone (trendione)	Anabolic	Finaplix; Revalor, Synovex (with Estradiol); Component (with estradiol and tylosin). DEA Schedule III.		
BANNED	S1		Trendione	Anabolic	Lacks FDA approval.		
BANNED	S0		Trestolone	Anabolic	Lacks FDA approval.		
BANNED	S3		Tretoquinol (trimetoquinol)	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
CONTROLLED	S7	C	Triamcinolone	Corticosteroid	Vetalog, Kenalog		0.5 ng/mL in urine
BANNED	S5		Triamterene	Diuretic	Dyrenium.		
BANNED	S0		Triazolam	CNS depressant	Halcion. DEA Schedule IV.		
BANNED	S0		Tribromoethanol	Anesthetic	Lacks FDA approval.		
BANNED	S0		Tricaine methanesulfonate	Anesthetic	Syncaine.		
CONTROLLED	S7	C	Trichlormethiazide	Diuretic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Trichloroethanol	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S0		Trichloroethylene	Anesthetic	Lacks FDA approval.		
BANNED	S0		Triclofos	Sedative	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Tridihexethyl	Anticholinergic	No FDA-approved product.		
BANNED	S0		Triflumeprazine	Sedative	Lacks FDA approval.		
BANNED	S0		Trifluoperazine	Antipsychotic	Generic.		
BANNED	S0		Trifluoromethylphenyl piperazine	Stimulant	Lacks FDA approval.		
BANNED	S0		Trifluperidol	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Triflupromazine	Antipsychotic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Triflupromazine	Antipsychotic	Discontinued, no FDA-approved product commercially available.		

BANNED	S0		Trihexyphenidyl	Anticholinergic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Trimecaine	Local anesthetic	Lacks FDA approval.		
BANNED	S0		Trimeprazine (alimemazine)	Antihistamine	Temaril-P [with prednisolone].		
BANNED	S4		Trimetazidine	Angina treatment	Lacks FDA approval.		
BANNED	S0		Trimethadione	Anticonvulsant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Trimethaphan	Antihypertensive/Anesthetic	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Trimipramine	Antidepressant	Generic.		
CONTROLLED	S7	B	Tripelennamine	Antihistamine	Re-Covr.		
BANNED	S0		Triprolidine	Antihistamine	Triacin-C (with codeine phosphate and pseudoephedrine hydrochloride).		
BANNED	S2		Triptorelin	Reproductive hormone modulator.	Triptodur, Trelstar.		
BANNED	S0		Trometamol (Tris hydroxymethylaminomethane [THAM].	Alkalinizing agent	Discontinued, no FDA-approved product is commercially available.		
CONTROLLED	S7	B	Tropicamide	Ophthalmic Anticholinergic	Mydriacyl.		
BANNED	S0		Tuaminoheptane	Stimulant	Lacks FDA approval.		
BANNED	S0		Tubocurarine (Curare)	Muscle relaxant	Plant alkaloid. Discontinued, no FDA-approved product commercially available.		
BANNED	S3		Tulobuterol	Beta-2 agonist-bronchodilator	Lacks FDA approval.		
BANNED	S0		Tybamate	Anxiolytic	Lacks FDA approval.		
BANNED	S0		Valdecoxib	NSAID	Discontinued, no FDA-approved product commercially available.		
CONTROLLED	S7	A	Valerenic acid	Sedative	Plant derived.		
BANNED	S0		Valnoctamide	Sedative/Hypnotic	Lacks FDA approval.		
BANNED	S0		Valproate Sodium	Anticonvulsant	Discontinued, no FDA-approved product commercially available.		
BANNED	S0		Valsartan	Antihypertensive	Diovan, Entresto (with sacubitril).		
BANNED	S0		Vardenafil	Phosphodiesterase inhibitor	Levitra.		
BANNED	S2		Vascular-Endothelial Growth Factor (VEGF).	Growth Hormone.			
CONTROLLED	S7	A	Vecuronium	Muscle relaxant	Generic.		
BANNED	S0		Vedaprofen	NSAID	Lacks FDA approval.		
BANNED	S0		Venlafaxine	Antidepressant	Pristiq.		
BANNED	S0		Veralipride	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Verapamil	Antihypertensive	Verelan, Calan.		
BANNED	S3		Vilanterol	Beta-2 agonist-bronchodilator	Trelegy, Ellipta.		
BANNED	S0		Viloxazine	Antidepressant	Qelbree.		
BANNED	S0		Vinbarbital	Hypnotic	Lacks FDA approval. DEA Schedule III.		
BANNED	S0		Vinylbital	Sedative/Hypnotic	Lacks FDA approval.		
CONTROLLED	S7	C	Warfarin	Anticoagulant	Coumadin, Jantoven.		
BANNED	S2		Xenon	HIF activating agent.			
BANNED	S5		Xipamide	Diuretic	Lacks FDA approval.		
CONTROLLED	S7	B	Xylazine	Sedative/Analgesic	Rompun, Anased	Detection Time: 72 hours. 200 mg single IV dose.	SL: 10 ng/mL U (as 4–OH xylazine); 0.05 ng/mL B.
BANNED	S0		Xylometazoline	Stimulant	Afrin, Vicks Sinex.		
CONTROLLED	S7	B	Yohimbine	Stimulant	Antagonil.		
BANNED	S0		Zafirlukast	Asthma prevention	Accolate.		
BANNED	S0		Zaleplon	CNS depressant	Sonata. DEA Schedule IV.		
BANNED	S1		Zeranol	Anabolic	Ralgro.		
BANNED	S6		Ziconotide	Neurotoxin	Prialt.		
BANNED	S0		Zileuton	Asthma prevention	Zyflo.		
BANNED	S1	(x)	Zilpaterol hydrochloride	Anabolic	Zilmax, Heifermax.		
BANNED	S0		Zimeldine	Antidepressant	Lacks FDA approval.		
BANNED	S0		Ziprasidone	Antipsychotic	Geodon.		
CONTROLLED	S7	A	Zolazepam	Sedative/Anxiolytic	Telazol [with tiletamine].		
BANNED	S6		Zoledronic acid	Bisphosphonate	Reclast.		
BANNED	S0		Zolmitriptan	Selective Serotonin Receptor Agonist.	Zomig.		

HISA listed as	HISA status	Penalty subclassification (specified substances are designated with 'x')	Substance	Action	Commercial name(s) (developmental names)	Detection time	Screening limit *
BANNED	S0		Zolpidem	Sedative/Hypnotic	Ambien. DEA Schedule IV.		
BANNED	S0		Zomepirac	Anticonvulsant	Lacks FDA approval.		
BANNED	S0		Zonisamide	Anticonvulsant	Zonegran.		
BANNED	S0		Zopiclone	Sedative/Hypnotic	Lunesta. DEA Schedule IV.		
BANNED	S0		Zotepine	Antipsychotic	Lacks FDA approval.		
BANNED	S0		Zuclopenthixol	Antipsychotic	Lacks FDA approval.		

*(Unless otherwise designated as a Threshold). Where no value is listed for serum or plasma the substance is controlled by Laboratory Limit of Detection. Unless otherwise specified, urine values are in *hydrolyzed* urine.

5000. Equine Testing and Investigations Standards

5010. Purpose

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

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

(c) The second purpose of the Testing and Investigations Standards is to establish rules for the efficient and effective gathering, assessment, and use of anti-doping and medication control intelligence, and for efficient and effective investigations into possible anti-doping and medication control rule violations.

5020. Definitions

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

5100. Standards for Testing

5110. Planning Effective Testing

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

(b) The Agency shall ensure that Covered Persons with a conflict of interest in the outcome of the Testing being contemplated are not involved in test planning or in the process of selection of Covered Horses for Sample collection.

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

5120. Risk Assessment

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

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

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

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

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

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

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

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

5130. Prioritizing Between Covered Horses, Types of Testing, and Samples

(a) The Agency should consider various factors in prioritizing the allocation of Testing resources. In addition, the Agency will use Target Testing to focus Testing resources where they are most needed within the overall pool of Covered Horses.

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

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

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

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

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

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

(6) repeated failure to meet whereabouts requirements;

(7) suspicious whereabouts filing patterns;

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

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

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

(11) injury;

(12) age and stage of career;

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

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

(c) Target Testing is a priority because random Testing, or even weighted random Testing, does not ensure that all of the appropriate Covered Horses will be sufficiently tested. Covered Horses may be tested at any time and at any place where they are located (*e.g.,* Racetrack, Training Facility, private facility). The Protocol does not impose any reasonable suspicion or probable cause requirement for Target Testing or Testing.

(d) Testing that is not Target Testing should be determined based on the Risk Assessment. Testing should be conducted using a documented system for such selection, such as weighted testing (where Covered Horses are ranked using pre-determined criteria to increase or decrease the chances of selection) or random testing (where no pre-determined criteria are considered, and Covered Horses are chosen arbitrarily from a list or pool of names). Testing that is weighted should be prioritized and conducted according to defined criteria which may take into account the risk factors to ensure that a greater percentage of at risk Covered Horses are selected.

(e) Based on the Risk Assessment and prioritization process described above, the Agency should determine to what extent each of the following types of Testing is required to effectively detect and deter doping and misuse of medication within the sport:

(1) TCO2 and Post-Race Sample collection on Race Day;

(2) Post-Work Sample collection following Timed and Reported Workouts;

(3) Out-of-competition Sample collection;
(4) Sample matrices to be considered:
(i) urine;
(ii) hair;
(iii) blood; or
(iv) other matrices or methodologies, as available.

5140. Sample Analysis, Retention Strategy, and Further Analysis

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

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

(1) Laboratory recommendations (when available);

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

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

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

5150. Coordinating With State Racing Commissions and Other Entities

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

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

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

5200. Notification

5210. Requirements Prior to Notification

(a) Testing without advance notice should be the method for Sample collection except in circumstances where advance notice is required to facilitate the Testing. If the Responsible Person is with the Covered Horse at the time of notification, the Responsible Person should be the first Person notified that the Covered Horse has been selected for Sample collection. In order to ensure that Testing is conducted on a without advance notice basis, the Agency shall ensure Testing selection decisions are only disclosed in advance of Testing to those who need to know in order for such Testing to be conducted. Any notification to a third party shall be conducted in a secure and confidential manner to minimize the risk that the Responsible Person or other Covered Person will receive any advance notice of a Covered Horse's selection for Sample collection.

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

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

(d) Information provided in the Covered Horse's whereabouts filing and registration with the Authority, or other equally reliable form of identification, shall be used by Sample Collection Personnel to confirm the identity of the Covered Horse. Confirmation of the Covered Horse's identity by any other method or failure to confirm the identity of the Covered Horse shall be documented, including through photographs, and reported to the Agency.

(e) The DCO or BCO shall establish the location of the selected Covered Horse and plan the approach and timing of notification, taking into consideration the specific circumstances of the location, schedule, and the situation in question (*e.g.,* Covered Horserace, Timed and Reported Workout, Vets' List Workout).

5220. Requirements for Notification

(a) Out-of-competition Sample collection.

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

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

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

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

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

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

(ii) that immediate access to the Covered Horse shall be granted, and (if

that is not possible because the Covered Horse is not present at the location), the Responsible Person has 6 hours to produce the Covered Horse for Sample collection, failing which significant Consequences may apply in accordance with Rule 3215;

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

(iv) that the Sample collection process shall take place in a secure location determined suitable by the DCO or BCO (*e.g.,* the horse's stall);

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

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

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

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

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

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

(6) The Sample Collection Personnel shall have the Responsible Person or Nominated Person sign an appropriate form to acknowledge and accept the notification of Sample collection. If the Responsible Person or Nominated Person refuses to sign the form, or evades notification, the Sample Collection Personnel should, if possible, inform the Responsible Person or Nominated Person of the Consequences of a failure to comply, and the Sample Collection Personnel (if not the DCO) shall immediately report all relevant facts to the DCO or BCO. When possible, the Sample Collection Personnel shall continue the Sample collection. The DCO shall document the facts in a detailed report and report the circumstances to the Agency.

(7) A Nominated Person may be replaced by another Nominated Person during the Sample collection process upon reasonable request to the Sample Collection Personnel so long as the new Nominated Person (i) falls within the scope of the definition of Nominated Person, (ii) completes the relevant portions of the Sample collection paperwork, and (iii) does not interfere with the Sample collection process. Any changes of Nominated Person during the Sample collection process shall be documented by the Sample Collection Personnel.

(b) Post-Race Sample collection.

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

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

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

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

(iii) of the location of the Test Barn;

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

(A) ensure that the Covered Horse remains under observation of Sample Collection Personnel, to the extent possible, until the completion of the Sample Collection Session;

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

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

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

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

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

(3) The Sample Collection Personnel shall notify the Responsible Person or Nominated Person and document the time and the individual notified (*e.g.,* by taking a photograph or by having the Responsible Person or Nominated Person sign an appropriate form or through such other reasonable and appropriate measure under the circumstances), and the Responsible Person or Nominated Person must sign an appropriate form to acknowledge and accept the notification no later than once in the Test Barn or other secure location. If the Responsible Person or Nominated Person refuses to sign the form, or evades the notification, the Sample Collection Personnel should, if possible, inform the Responsible Person or Nominated Person of the Consequences of a failure to comply, and the Sample Collection Personnel (if not the DCO or BCO) shall immediately report all relevant facts to the DCO or BCO. When possible, the Sample Collection Personnel shall continue the Sample collection. The DCO or BCO shall document the facts in a detailed report and report the circumstances to the Agency.

(4) From the time that a Covered Horse is tagged or identified for Sample collection until the end of the Sample collection process, the Sample Collection Personnel shall keep the Covered Horse under observation or ensure the Covered Horse is in a secure location (a stall, for example).

(5) A Nominated Person may be replaced by another Nominated Person

during the Sample collection process upon reasonable request to the Sample Collection Personnel, so long as the new Nominated Person (i) falls within the scope of the definition of Nominated Person, (ii) completes the relevant portions of the Sample collection paperwork, and (iii) does not interfere with the Sample collection process. Any changes of Nominated Person during the Sample collection process shall be documented by the Sample Collection Personnel.

(c) Pre-race Sample collection.

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

(d) Post-Work Sample collection.

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

5230. Requests for Delay

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

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

(1) participation in the winner's circle;

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

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

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

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

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

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

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

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

5300. Preparing for the Sample Collection Session

5310. General Requirements

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

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

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

(i) an enclosed area for Covered Horses to walk in or adjacent to the Test Barn that is large enough to accommodate several horses and allow for continuous observation of the Covered Horses;

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

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

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

(v) a table or other suitable surface;

(vi) access to hot and cold running water;

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

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

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

(c) For out-of-competition Sample collection, the DCO or BCO will determine a suitable location to be used for the Sample Collection Session. If at a stable, by default the Covered Horse's own stall should be used.

5320. Sample Collection Equipment

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

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

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

(2) have a Tamper Evident sealing system;

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

(4) be clean and sealed prior to use;

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

(i) be able to withstand the handling conditions and environment in which the equipment will be used or subjected to, including, but not limited to, transportation, Laboratory analysis, and long-term storage;

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

(iii) if the Sample will be transported or stored frozen, withstand temperatures

of up to −80 °C and a minimum of three (3) freeze/thaw cycles;

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

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

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

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

(viii) be able to be resealed after initial opening by a Laboratory to maintain the integrity of the Sample and Chain of Custody in accordance with the requirements for long-term storage and Further Analysis; and

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

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

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

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

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

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

(1) a needle for blood sampling; and

(2) blood collection tubes, each with a capacity to contain a minimum of 8 mL of blood, to ensure a minimum total of 30 mL of blood is collected (except for TCO2 testing, where a lesser volume may be collected at the discretion of the Agency).

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

5400. Conducting the Sample Collection Session

5410. Collection of Samples

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) The Sample Collection Personnel shall collect the Sample from the Covered Horse according to the following protocol(s) for the specific type of Sample collection:

(1) Rule 5420: Collection of urine Samples;

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

(3) Rule 5440: Collection of hair Samples.

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

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

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

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

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

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

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

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

(6) the name of the Covered Horse;

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

(8) the color of the Covered Horse;

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

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

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

(12) the Sample code number(s);

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

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

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

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

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

(18) any required Laboratory information on the Sample (*e.g.,* for

urine or blood Sample, its volume; for hair Sample, mane/tail and pulled/cut);

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

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

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

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

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

(k) The Agency may require the Sample Collection Personnel to complete supplemental documentation regarding the Sample Collection Session. For example, any anomalous behavior by the Responsible Person, Nominated Person, or other Covered Persons or Persons associated with the Covered Horse or Responsible Person, or behavior with the potential to compromise the Sample collection shall be recorded in detail by the Sample Collection Personnel. If the Covered Horse requires any emergency medical treatment, that shall be recorded in detail by the Sample Collection Personnel.

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

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

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

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

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

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

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

5420. Collection of Urine Samples

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

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

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

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

(e) The relevant Sample Collection Personnel shall ensure as unobstructed a view as possible of the Sample leaving the Covered Horse's body and shall continue to observe the Sample after provision until the Sample is securely sealed.

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

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

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

(i) Once the volume of urine provided by the Covered Horse is deemed sufficient, the relevant Sample Collection Personnel will bring the Sample to the designated processing area.

(j) The relevant Sample Collection Personnel will select the Sample collection kit and will open, inspect, and confirm Sample codes numbers within the kit match and ask the Responsible Person or Nominated Person to confirm the same.

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

(l) Once the Sample collection kit has been selected, the relevant Sample Collection Personnel will pour and split the urine Sample into A and B Sample

collection bottles within the view of the Responsible Person or Nominated Person.

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

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

(o) Urine should only be discarded when both the A and B bottles or containers have been filled to the maximum amount they can hold and have been sealed. Any excess urine should be disposed of into a drain (ground drain or sink) or into a bin or waste pile, if necessary. The Responsible Person or Nominated Person shall be given the option to observe the disposal of any residual urine not sent to the Laboratory for analysis.

5430. Collection of Blood Samples

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

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

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

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

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

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

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

(h) Subject to paragraph (l) below, the BCO will collect the amount of blood that will adequately satisfy the relevant analytical requirements for the Sample analysis to be performed. The minimum total volume requirement is 30 mL whole blood, plasma, or serum, with each collection tube containing a minimum of 8 mL.

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

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

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

(l) Total carbon dioxide (TCO2):

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

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

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

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

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

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

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

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

5440. Collection of Hair Samples

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

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

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

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

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

(e) the Sample should be secured tightly with an elastic band, or equivalent, and oriented to clearly mark the ends cut or pulled from the Covered Horse; and

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

5450. Sample Collection Personnel Requirements

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

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

(2) Sample Collection Personnel shall agree to undergo screening required by

the Agency (*e.g.,* background checks, conflicts of interest); and

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

(b) Conflicts.

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

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

(i) are related to, employed or otherwise engaged by, or otherwise affiliated with any Equine Constituencies, excluding State Racing Commissions and Racetracks, if the Sample Collection Personnel have met the other requirements set forth by the Agency;

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

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

(iv) appear to have private or personal interests that detract from their ability to perform their duties with integrity and in an independent and purposeful manner.

(c) Training.

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

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

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

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

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

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

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

(5) The Agency should ensure that Sample Collection Personnel are adequately trained to carry out their responsibilities in a manner respectful of any Covered Persons who are of a different race, religion, sex, national origin, sexual orientation, age, citizenship, disability, gender identity, or Veteran status.

(d) Credentialing.

(1) The Agency shall establish a system for credentialing and re-credentialing DCOs and BCOs. DCOs and BCOs shall have either a credential including their name, photograph, and date of expiration, or a letter of authority from the Agency and a Federal or State issued identification. The Agency may determine what information or authorization documentation to require for other Sample Collection Personnel.

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

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

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

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

5500. Storage and Transportation

5510. Storage and Custody of Samples Prior to Analysis

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

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

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

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

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

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

(d) The Agency shall develop a system for recording the Chain of Custody of Samples and receiving Sample Collection Session documentation to ensure that each Sample is securely handled and the documentation for each Sample is completed.

5520. Transport of Samples and Documentation

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

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

(c) State Racing Commissions may select a Laboratory at which the A Samples (or official TCO2 Samples) collected in its state shall be analyzed. If specific analysis requested by the Agency cannot be performed at the selected Laboratory, the Agency may have the Sample sent to another Laboratory that can conduct the requested analysis. Each year the State Racing Commissions must make their Laboratory designation for all Samples collected within its state on or before September 30th of the year prior to the designation taking effect. If a State Racing Commission fails to select a Laboratory by this deadline, the Agency shall select the Laboratory for that particular state. The Agency may allow for a State Racing Commission to change its selection of Laboratory outside of the time-period set forth above if a reasonable request is made (as determined by the Agency).

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

(e) The Agency will have the ability to confirm, if necessary, that Samples

and related documentation arrived at the Laboratory. The Laboratory shall report any irregularities to the Agency with respect to the condition of Samples upon arrival in accordance with the Laboratory Standards.

(f) The Agency shall develop a system to ensure that, where required, instructions for the type of analysis to be conducted are provided to the Laboratory that will be conducting the analysis. In addition, the Agency shall provide the Laboratory with information as required for result reporting and statistical purposes, including whether long-term storage is required.

(g) Documentation identifying the Covered Horse and Responsible Person or Nominated Person shall not be included with the Samples or documentation sent to the Laboratory that will be analyzing the Samples.

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

5530. Ownership and Retention of Samples and Retention of Documentation

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

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

5600. Standards for Intelligence Gathering

5610. Purpose

The Agency shall ensure that it is able to: obtain, assess, and process anti-doping and medication control intelligence from all available sources to help deter and detect doping and misuse of medication and inform effective, intelligent, and proportionate test planning; plan Target Testing; and conduct investigations as required by the Protocol. The objective of this Rule is to establish standards for the efficient and effective gathering, assessment, and processing of such intelligence for these purposes.

5620. Gathering Intelligence

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

(b) The Agency shall ensure that anti-doping and medication control intelligence obtained or received from a confidential source or in a non-public fashion is handled securely and confidentially, that sources of intelligence are protected, that the risk of leaks or inadvertent disclosure is properly addressed, and that intelligence shared with the Agency in a matter intended to be confidential is processed, used, and disclosed only for any legitimate legal, law enforcement, regulatory, anti-doping, medication control, integrity, disciplinary, horse welfare, or safety purposes.

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

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

5630. Assessment and Analysis of Intelligence

(a) The Agency should ensure that it is able to assess all anti-doping and medication control intelligence upon receipt for relevance, reliability, and accuracy, taking into account the nature of the source and the circumstances in which the intelligence has been captured or received.

(b) All relevant anti-doping and medication control intelligence obtained or received by the Agency should be collated and analyzed to establish patterns, trends, and relationships that may assist the Agency in developing an effective anti-doping and medication control strategy and in determining (where the intelligence relates to a particular case) whether there is reasonable suspicion that an Anti-Doping Rule Violation or Controlled Medication Rule Violation may have been committed, such that further investigation is warranted.

5640. Intelligence Outcomes

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

(a) developing, reviewing, and revising test distribution planning;

(b) determining when to conduct Target Testing; or

(c) creating targeted intelligence files to be referred for investigation.

5700. Standards for Investigations

5710. Purpose

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

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

(2) the investigation of any other analytical or non-analytical information or intelligence where there is reasonable suspicion to suspect that an Anti-Doping Rule Violation or Controlled Medication Rule Violation may have been committed;

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

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

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

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

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

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

5720. Investigating Possible Violations

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

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

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

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

(e) The Agency shall ensure that investigations are conducted fairly, objectively, and impartially at all times. The conduct of investigations, the evaluation of information and evidence identified in the course of that investigation, and the outcome of the investigation, should be fully documented.

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

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

5730. Obtaining Investigative Information

(a) General. The Agency should make use of all investigative resources reasonably available to it to conduct its investigation. These resources may include: obtaining information and assistance from other entities pursuant to Rule 5620(d); investigative powers conferred under applicable rules (including inspection, examination, and seizure, production of documents, subpoenas, and interviews); and the power to suspend a period of Ineligibility imposed on a Covered Person in return for Substantial Assistance in accordance with the Protocol. Without limitation, the Agency may utilize the investigative tools set forth in paragraphs (b) through (f) of this Rule in relation to investigations and inquiries of possible violations of the Protocol.

(b) Inspection, examination and seizure.

(1) The Agency shall have access to the books, records, offices, racetrack facilities, and other places of business of Covered Persons that are used in the care, treatment, training, or racing of Covered Horses.

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

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

(d) Production of documents and information.

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

(2) The Agency may require production of any mobile phones, computers, tablets, other electronic devices, books, documents and records (including telephone or financial records whether currently in the direct possession of a Covered Person or a third person who may be directed by the Covered Person to provide the information) that may be relevant to any investigation, inquiry, hearing, or proceeding, and that are used in the care, treatment, training, or racing of Covered Horses.

(e) Subpoenas. The Agency may request that the Authority issue a subpoena to a Person to appear or to answer questions or produce evidence related to anti-doping and medication control matters. A subpoena may direct the witness to: appear at a specific time and place to testify; produce designated evidence by a specific time; or permit the Agency to inspect premises at a specific time. A subpoena must be issued under the signature of a designated person from the Authority. If the Covered Person fails to comply with a subpoena, the Agency or Authority may seek enforcement of the subpoena in any of the district courts of the United States within the jurisdiction of which such inquiry is being conducted. Additionally, the arbitrator(s), IAP member(s), administrative law judge, or Commission considering a case arising under the Protocol may draw an adverse inference against a Covered Person who fails to comply with a valid subpoena, regardless of whether a court has been required to enforce the subpoena or has found the Covered Person in contempt.

(1) This issuance of a subpoena and compliance therewith is independent of the Agency's powers to inspect and obtain evidence without a subpoena and a Covered Persons' duty to cooperate under the Protocol. In addition to a rule violation for refusal to cooperate, a refusal to cooperate can result in imposition of an adverse inference against a Covered Person by the arbitrator(s), IAP member(s), administrative law judge, or Commission.

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

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

(ii) the indispensability of the information to the success of the

investigation or establishing a violation; and

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

(f) Interviews.

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

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

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

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

5740. Investigation Outcomes

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

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

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

(d) The Agency may include information from its investigations in reports made to the Authority, Congress, State Racing Commissions, or other appropriate bodies, regardless of whether the information relates to one or more rule violations. The fact that information was included in such a report shall not be a defense in any proceeding involving a potential rule violation.

6000. Equine Standards for Laboratories and Accreditation

Rule 6010. Equine Standards for Laboratories and Accreditation

(a) The main purpose of these Laboratory Standards is to ensure that Laboratories report valid test results based on reliable evidentiary data and to facilitate harmonization in Analytical Testing of Samples by Laboratories.

(b) The Laboratory Standards set 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 Laboratory Standards include, 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 Laboratory Standards also set out requirements and guidance in relation to Sample custody and storage, Analytical Testing, and some aspects of Results Management.

(c) Compliance with the Laboratory Standards 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 Laboratory Standards 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 these Laboratory Standards 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.

(d) Otherwise undefined capitalized terms used in these Laboratory Standards have the meanings given to them in Rule 1020.

Rule 6020. Technical Documents

(a) Technical Documents may be drafted by the Laboratory Expert Group or Agency and circulated for stakeholder consultation before being finalized. Technical Documents will be approved by the Agency, and Authority (where appropriate), and published on the Agency website. Once approved, a relevant Technical Document becomes an integral part of the Laboratory Standards and supersedes any previous publication on a similar topic, including Technical Letter(s) or the Laboratory Standards.

(b) 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 this Rule 6020 and shall occur no later than the effective date.

(c) 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 remediation requirements. In exceptional circumstances, a suspension of the Laboratory's HEAL accreditation may be warranted, as determined by the Agency.

(d) 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.

(e) 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.

(f) 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.

(g) 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 (where appropriate), provided that the

requirements of the Technical Document have been implemented and documented appropriately by the Laboratory.

(h) 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.

Rule 6030. Technical Letters

(a) Technical Letters may be 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) or Prohibited Method(s) or on the application of specific Laboratory procedures. Technical Letters are modified or withdrawn by the Agency, as appropriate.

(b) Technical Letters will be drafted and approved by the Agency, and Authority (where appropriate), in consultation with relevant scientific experts, and published on the Agency's website. Technical Letters become effective immediately, unless otherwise specified by the Agency. Technical Letters may require actions (*e.g.,* validation of new Analytes or modifications to Analytical Testing Procedures, the procurement of Reference Material(s) or Reference Collection(s)), which may justify that its application cannot be immediate. In such cases, the Agency shall make a time provision for implementation and specify an effective date for the Technical Letter.

(c) Once approved, a relevant Technical Letter becomes an integral part of the Laboratory Standards and supersedes any previous publication on a similar topic, including Technical Document(s) or the Laboratory Standards.

(d) 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.

Rule 6040. Laboratory Guidelines

(a) Laboratory Guidelines may be issued to provide direction to the Laboratories on new Analytical Methods or procedures approved by the Agency. Laboratory Guidelines will be modified or deleted by the Agency, as appropriate.

(b) Laboratory Guidelines will be approved by the Laboratory Expert Group (LabEG). Laboratory Guidelines are provided to Laboratories only and are not published on the Agency website.

(c) 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.

Rule 6050. Technical Notes

(a) Technical Notes may be issued to Laboratories to provide detailed technical guidance on the performance of specific Analytical Methods or procedures.

(b) Technical Notes will be approved by the LabEG. Technical Notes are provided to Laboratories only and are not published on the Agency website.

(c) 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.

Rule 6060. Sample Analysis

(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) or their Metabolite(s), or Marker(s) of Use of Prohibited Substances or Prohibited Methods in an equine Sample.

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

Rule 6070. Racing Medication and Testing Consortium Accredited Laboratories

(a) These Laboratory Standards will replace current Racing Medication and Testing Consortium (RMTC) accreditation, although a transition phase which may include RMTC conducting the accreditation program may be agreed between the Agency and RMTC.

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

6100. Laboratory Accreditation and Operating Standards

Rule 6110. Process and Requirements for HEAL Laboratory Accreditation

(a) Applicant laboratory for HEAL accreditation. Only a laboratory that satisfies the criteria in this Rule 6110 may apply to become a candidate laboratory for HEAL accreditation.

(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 or public institution).

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

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

(1) Description of the candidate laboratory. 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:

(i) Staff list and their qualifications, including description of any relevant

anti-doping experience and a list of relevant scientific publications by laboratory staff;

(ii) 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);

(iii) 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;

(A) 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);

(B) IT security. Implementation of firewalls and other cyber security measures consistent with best practice and any applicable governmental regulations;

(C) Information Technology (IT) infrastructure. Implementation of a data and information management system (*e.g.,* LIMS) and a central server/intranet which allows secure data handling.

(iv) 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);

(v) List of validated Initial Testing Procedures 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);

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

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

(viii) Plans to ensure compliance with laboratory independence and impartiality requirements before receiving HEAL accreditation (and if this requirement is covered by other accreditation, such as ISO/IEC 17025, the laboratory may refer to it);

(ix) Status and scope of ISO/IEC 17025 accreditation; and

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

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

(2) Payment of initial accreditation fee. 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. The accreditation process will not commence until the fee is agreed upon.

(3) Compliance with the Code of Ethics. 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 his or her behalf (unless approved in writing and in advance by the Agency and on the condition that Samples will be treated as a Sample under the Protocol, and proceedings may be brought against the relevant Covered Person(s) if evidence of an Anti-Doping Rule Violation or a Controlled Medication Rule Violation emerges).

(4) Pre-probationary testing and on-site assessment. If this is covered by another accreditation, such as ISO/IEC 17025, the laboratory may refer to this paragraph (4).

(i) 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.

(ii) As part of the PPT, the candidate laboratory shall be required to analyze at least 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 the Rule 6200 and 6400 Series, respectively.

(iii) 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 paragraph (e) of Rule 6260) within 6 weeks, unless otherwise requested by the candidate laboratory and agreed to by the Agency.

(A) 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 10 days of the request or as otherwise indicated by the Agency.

(B) For selected EQAS samples with Negative Findings, the Agency may request all, or a portion of, the Initial Testing Procedure data.

(iv) 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 30 days, or as otherwise indicated by the Agency.

(v) In addition, the Agency shall provide an assessment report regarding the outcomes of the on-site assessment, including any identified nonconformities, 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 30 days, or as otherwise indicated by the Agency.

(vi) The nonconformities identified in the Agency assessment report shall be satisfactorily addressed and the recommendations for improvement shall 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.

(5) ISO/IEC 17025 accreditation.

(i) ISO/IEC 17025 accreditation is a critical and mandatory precondition for HEAL accreditation.

(ii) The Agency will consider a candidate laboratory application for HEAL accreditation only if the laboratory has obtained (or is in the process of obtaining) ISO/IEC 17025 accreditation. ISO/IEC 17025 accreditation must be conferred prior to an applicant receiving full HEAL accreditation.

(iii) The accreditation body, which may be specified by the Agency, shall be an International Laboratory Accreditation Cooperation (ILAC) full member that is a signatory to the ILAC

Mutual Recognition Arrangement (ILAC MRA) for testing activities as defined in ISO/IEC 17025.

(iv) The candidate laboratory shall (in a timely manner) send to the Agency a summary of the assessment report and any corrective or preventive action documentation addressing nonconformities.

(6) Analytical Testing Procedures. 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.

(7) Laboratory independence and impartiality. 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 paragraph (c) of Rule 6130.

(8) Professional liability insurance coverage. 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 $5,000,000 annually.

Rule 6120. The Agency Accredited Laboratory; Obtaining HEAL Accreditation

(a) The Agency probationary HEAL accreditation.

(1) Upon satisfactory completion of the candidate laboratory requirements (as per Rule 6110), 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.

(2) A probationary laboratory must comply with the requirements of accredited laboratories, including the requirements for maintaining accreditation.

(3) The probationary period is 2 years or following the analysis of 2,500 Samples, whichever comes later. In circumstances where the laboratory was previously accredited by the RMTC, the Agency may exercise its discretion to reduce or eliminate the probationary period.

(b) The Agency pre-final accreditation.

(1) 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) 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.

(2) As part of the FAT, the probationary laboratory shall analyze a minimum of 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 Rules 6200 and 6400, respectively.

(3) Compliance with the scope of ISO/IEC 17025 accreditation, the Laboratory Standards, and other procedures required by the Agency (*e.g.,* Technical Documents, Technical Letters) will be assessed. The FAT shall assess both the scientific competence and the capability of the probationary laboratory to manage multiple Samples.

(4) The probationary laboratory shall successfully report the results for the blind EQAS samples in the FAT to the Agency in accordance with paragraph (e) of Rule 6260 within 6 weeks of receipt the samples, unless otherwise specified by the Agency or otherwise requested by the laboratory and agreed to by the Agency.

(5) 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 10 days of the Agency request, or as otherwise indicated by the Agency.

(6) For EQAS samples with Negative Findings, the Agency may request all or a portion of the Initial Testing Procedure data.

(7) 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 30 days, or as otherwise indicated by the Agency.

(8) 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 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 shall be implemented before accreditation will be granted.

(c) The Agency recommendation for accreditation.

(1) 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 Rules 6110 and 6120.

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

(3) 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 shall not be accredited, the laboratory will have a maximum of 6 additional months to correct and improve any pending nonconformities. The provision of documentation, the analysis of additional EQAS samples, or an additional assessment (on-site, remotely, or as a documentary audit, as determined by the Agency) may be required and, if so, will be conducted at the probationary laboratory's expense. A probationary laboratory that fails to provide satisfactory improvements after 6 months, as determined by the Agency, may be required to renew its candidacy as described in Rule 6110 or to restart the probationary phase of accreditation in accordance with paragraph (a) of this Rule 6120.

(d) Issuing and publishing of HEAL accreditation certificate. 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.

Rule 6130. Maintaining HEAL Accreditation

(a) Maintain ISO/IEC 17025 accreditation. The Laboratory shall maintain accreditation to ISO/IEC 17025, with primary reference to the analysis of Samples, granted by an accreditation body, which may be specified by the Agency, and which shall be an International Laboratory Accreditation Cooperation (ILAC) full member that is a signatory to the ILAC Mutual Recognition Arrangement (ILAC MRA) for testing activities as defined in ISO/IEC 17025. Flexible scope of accreditation must be included in the Laboratory's scope of accreditation.

(b) Participation in the Agency EQAS program. Laboratories are required to participate in the Agency EQAS on a continuous basis and meet the performance requirements of the EQAS as described in the Rule 6200 Series.

(c) Laboratory independence and impartiality.

(1) 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. Laboratories shall comply with these requirements of administrative and operational independence by January 1, 2023, unless otherwise approved by the Agency.

(2) In order to be operationally independent, the Laboratory shall manage its own affairs without hindrance, interference, or direction from any Person, except in accordance with the Laboratory Standards. 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.

(3) 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, and other relevant scientific decisions. This does not prevent the Laboratory from receiving research grants or other financial support from its host organization (*e.g.,* university, public institution), anti-doping organizations, sport organizations, governments, or other sponsors, while following applicable accounting regulations in connection with the receipt and management of those funds.

(d) Document compliance with the Code of Ethics.

(1) The Laboratory shall comply with the provisions of the Code of Ethics.

(2) 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 documentation to indicate their agreement to the Code of Ethics. The Laboratory may be asked to provide documentation of compliance with the provisions of the Code of Ethics.

(3) 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 promptly report to the Agency. However, if Laboratory staff suspect that the Laboratory Director may have breached the Code of Ethics, the Laboratory staff shall promptly report the alleged breaches of the Code of Ethics directly to the Agency. The Laboratory Director or the Agency, as applicable, shall immediately and thoroughly investigate any alleged breach of the Code of Ethics.

(4) 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.

(e) Document implemented research and development activities.

(1) 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.

(2) 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.

(3) 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 in Rule 6620.

(f) Document implemented sharing of knowledge.

(1) 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 is encouraged to make at least one annual contribution to an anti-doping symposium or conference. Laboratories are encouraged to: participate in collaborative research projects with other Laboratories; exchange experience and protocols with other Laboratories; arrange for visits of specialists with other Laboratories; and provide training to other Laboratories and probationary laboratories in specific areas of Analytical Testing.

(2) 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.

(g) Maintain professional liability insurance coverage. Laboratories shall provide documentation to the Agency including evidence that professional liability risk insurance coverage is maintained of no less than $5,000,000 annually (for example, evidence of timely payment of applicable fees and premiums).

(h) Maintain minimum number of Samples.

(1) To maintain proficiency in Analytical Testing, Laboratories are required to analyze a minimum of 2,500 Samples provided annually by the Agency. To determine the minimum number of Samples, each urine Sample and blood Sample analyzed by the Laboratory (excluding Samples submitted for TCO2 analysis only), regardless of whether they are collected as a ''paired'' Sample, shall count as an individual Sample. The Agency will monitor the number of Samples tested by the Laboratory. Except where the Agency fails to send the minimum annual number of Samples to the Laboratory, if the number of Samples falls below the minimum, the

Laboratory's HEAL accreditation may be suspended in accordance with Rule 6510.

(2) 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, conduct a documentary audit, or an on-site or remote (online) assessment, at its discretion, to assess the status of the Laboratory's operations.

(i) Laboratory Analytical Testing Procedures and services. 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 shall cooperate with the Agency by providing other relevant information regarding Testing plans (*e.g.,* Laboratory analytical capabilities).

(j) Participating in the Agency/accreditation body re-assessments and continuous assessments during the accreditation cycle.

(1) The assessment team shall include at least one Laboratory Standards-trained assessor selected by the accreditation body for the assessment/re-assessment.

(2) The Laboratory shall (in a timely manner) send to the Agency a summary of the assessment report and any corrective or preventive action documentation addressing nonconformities.

(3) 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.

(4) The Agency Laboratory assessment. The Agency reserves the right to conduct documentary audits, as well as inspect and assess the Laboratory, through on-site or remote (online) 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.

(5) As part of an announced or unannounced Laboratory assessment, the Agency retains the right to request copies of Laboratory documentation or request Further Analysis of selected A or B Samples, either on-site or in any Laboratory selected by the Agency.

Rule 6140. The Agency Monitoring of Accreditation Status

(a) The Agency shall regularly review the compliance of Laboratories with the requirements listed in the Laboratory Standards 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.

(b) Maintenance of HEAL accreditation. Compliance with all the requirements established in Rule 6130, 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.

(c) Issuing and publication of accreditation certificate. 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 website.

6200. The Agency External Quality Assessment Scheme

Rule 6210. The Agency External Quality Assessment Scheme

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.,* Laboratory Standards, 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.

Rule 6220. Types of EQAS

(a) Blind EQAS. 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.

(b) Double-blind EQAS. 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.

(c) Educational EQAS.

(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.

(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.

(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 before the subsequent application of the Analytical Testing Procedure to the routine analysis of Samples.

Rule 6230. Number of EQAS Samples

(a) 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.

(b) Each year, the EQAS program will consist of:

(1) At least 15 blind EQAS samples, distributed by the Agency in multiple rounds;

(2) At least 5 double-blind EQAS samples, distributed by the Agency in multiple rounds; and

(3) At least 3 of the above EQAS samples will contain Threshold Substances.

(c) 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:

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

(2) Substantiated intelligence information received by the Agency indicating questionable or unsatisfactory Laboratory performance;

(3) 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; and

(4) As part of the Agency's Laboratory assessments.

Rule 6240. Composition of EQAS Samples

(a) EQAS samples may or may not contain Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s).

(b) Blank EQAS samples. Blank EQAS samples do not contain Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s).

(c) Adulterated EQAS samples. 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, or to 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).

(d) EQAS samples containing Prohibited Substance(s), their Metabolite(s) or Marker(s), or the Marker(s) of Prohibited Method(s).

(1) 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 or its Metabolite(s) or its Marker(s).

(2) EQAS samples may be spiked with Prohibited Substance(s) or their Metabolite(s) or Marker(s) but, where appropriate, may be 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.

(3) An EQAS sample 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.

(4) Double-blind EQAS samples shall be representative of Samples. Therefore, to the extent possible (in consideration, for example, of technical or ethical constraints, availability of the pharmaceutical grade substance), double-blind EQAS samples containing Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) shall 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).

(5) 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 or its Metabolite(s) or Marker(s) equal to or greater than (≥) the applicable MRPL; concentrations of the Prohibited Substance or its Metabolite(s) or Marker(s) between 50% of the MRPL 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 in a Post-Race Sample only), will normally be present in estimated concentrations greater than (≤) 120% of the applicable Minimum Reporting Level; or concentrations of the Prohibited Substance 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).

(6) 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 any relevant Technical Document(s) or Laboratory Guidelines; or less than (<) 50% of the Threshold for those Threshold Substances whose presence shall be reported if detected in the presence of diuretics or masking agents.

Rule 6250. Laboratory Analytical Testing Procedures Used in EQAS

All procedures associated with the Analytical Testing of the EQAS samples by the Laboratory are to be conducted in a manner substantially 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 Standard Operating Procedures are to be employed in the analysis of EQAS samples (*i.e.,* using the Initial Testing Procedures and Confirmation Procedures applied in routine Analytical Testing).

Rule 6260. Reporting of EQAS Results

(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.

(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.

(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 control assessment.

(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).

(e) Reporting blind EQAS results.

(1) The Laboratory shall report the results of blind EQAS samples to the Agency in the same manner as specified for routine Samples (see Rule 6316) 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).

(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. Failure to report results of blind EQAS samples will be considered a false Negative Finding(s).

(f) Reporting double-blind EQAS results.

(1) The Laboratory shall report the results of double-blind EQAS samples as per Rule 6316.

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

(3) Failure to report double-blind EQAS results within this timeframe or, subject to an extension of this deadline granted by the Agency pursuant to subparagraph (2) above, within the agreed or the Agency-approved deadline, will be considered a false Negative Finding(s).

(g) Reporting educational EQAS results.

(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 or in the subsequent educational EQAS report and will be considered a false Negative Finding(s).

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

(h) Reporting results for EQAS samples containing Non-Threshold Substances. 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, including the Prohibited Substance(s) (*e.g.,* parent compound(s), if applicable) and all identified Metabolite(s) 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).

(i) Reporting results for EQAS samples containing Threshold Substances.

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

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

6300. Analysis of Samples

Rule 6301. Application of ISO/IEC 17025 to the Analysis of Samples

(a) Introduction and scope. This section of the Laboratory Standards 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 any 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.

(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 3 main categories of processes:

(1) structural and resource requirements;

(2) process requirements; and

(3) management requirements.

Rule 6302. Subcontracting Analysis

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

(1) A specific technology or Analyte(s) that are not within the Laboratory's scope of ISO/IEC 17025 accreditation;

(2) An Analytical Testing Restriction decision;

(3) Other valid explanations, such as a need for higher sensitivity or specific equipment or expertise, temporary workload or technical incapacity;

(4) 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);

(5) 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.

(b) 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.

Rule 6303. Samples With Irregularities

(a) 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.

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

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

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

(3) Sample identification is questionable. For example, if the number on the Sample container does not match the Sample identification number on the Sample collection documentation;

(4) 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;

(5) Sample identification numbers are different between the A and the B Sample containers of the same Sample;

(6) Tampering or adulteration of the Sample is evident;

(7) Sample is not sealed with Tamper Evident device or not sealed upon receipt;

(8) Sample volume does not meet the suitable volume for analysis or is otherwise inadequate to perform the

Analytical Testing menu requested by the Agency;

(9) The Sample contains foreign objects, such as insects; or

(10) The Sample condition(s) is unusual (*e.g.,* color, odor, presence of turbidity or foam in a urine Sample, color, hemolysis, freezing or clotting of a blood Sample, or unusual differences in Sample appearance (such as color or turbidity) between the A and the B Samples).

(c) When an analysis on a Sample with documented irregularities is performed, the Laboratory shall record the irregularities in the test report.

Rule 6304. Sample Splitting Procedure

(a) 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 consult with the Agency regarding whether it is appropriate to split the other Sample container (A or B, as applicable), provided that it is properly sealed. The Agency should inform the Laboratory of its decision in writing within 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,'' including the noted Sample irregularities and the documented reasons if provided by the Agency.

(b) 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 the B Confirmation Procedure(s), if necessary.

(c) The process of opening and splitting the Sample and resealing of the remaining second fraction shall be conducted in accordance with Rule 6312 for a customary B Sample opening.

(d) 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 practicable 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.

Rule 6305. Initial Storage and Sample Aliquoting for Analysis

(a) The Aliquot preparation procedure for any Initial Testing Procedure 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 tips) to take Aliquots for Confirmation Procedures.

(b) Urine Samples. 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.

(1) For urine Samples, the Laboratory shall obtain, following proper homogenization of the Sample, an initial Aliquot containing enough Sample volume for all analytical procedures (*i.e.,* all Initial Testing Procedures 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.

(2) The Laboratory shall measure the pH and specific gravity of urine Samples once, using one Aliquot, during the Initial Testing Procedure 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.

(3) Urine A Samples shall 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.

(c) Blood Samples. The Laboratory shall follow any applicable Agency procedures, Technical Document(s), and Technical Letter(s) for handling and storing blood Samples.

Rule 6306. Selection and Validation of Analytical Testing Procedures

(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.

(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.

(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).

(d) Validation of Analytical Testing Procedures for Non-Threshold Substances. The Laboratory shall develop, as part of the method validation process, appropriate standard solutions for detection 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.

(1) Validation of Initial Testing Procedures for Non-Threshold Substances.

(i) The Laboratory shall validate the Selectivity, carryover, reliability of detection at the MRPL and Limit of Detection (LOD) for the Initial Testing Procedure 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).

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

(iii) If there is no available Reference Material, an estimate of the detection capability of the Initial Testing Procedure (*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.

(2) Validation of Confirmation Procedures for Non-Threshold Substances. 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:

(i) 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 any applicable Agency procedures, Technical Document, Technical Letter, or Laboratory Guidelines. The Confirmation Procedure shall be able to discriminate between Analytes of closely related structures;

(ii) 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 any applicable Agency procedures, Technical Document, Technical Letter, or Laboratory Guidelines). The LOI shall be lower than the applicable MRPL;

(iii) 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; and

(iv) Carryover: The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis. Elimination of ''injection memory'' effect is demonstrated by injecting a blank control sample for the Analyte in question, prepared in the Sample matrix, immediately prior to the Sample of interest.

(3) Validation of Analytical Testing Procedures for Threshold Substances.

(i) 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 shall be used for quantification, if available.

(ii) For the application of affinity-binding assays, or other methods as applicable, to the analysis of Threshold Substances, the Laboratory shall follow any applicable Agency procedures and Technical Document, and should follow any relevant Laboratory Guidelines.

(4) Validation of Initial Testing Procedures for Threshold Substances.

(i) The Laboratory shall validate Initial Testing Procedures that are Fit-for-Purpose, in accordance with any applicable Technical Document(s), Technical Letter(s), or Laboratory Guidelines.

(ii) For chromatographic-mass spectrometric Initial Testing Procedures, 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.

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

(iv) In order to account for a possible underestimation of concentrations of Threshold Substances during non-quantitative Initial Testing Procedures, 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.

(v) The estimation of Measurement Uncertainty (MU) is not required during the validation of Initial Testing Procedures, unless otherwise specified.

(5) Validation of Confirmation Procedures for Threshold Substances. 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:

(i) Selectivity, LOI, robustness, and carryover;

(ii) 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, in accordance with the LOQ values required in relevant Technical Document(s) or in consideration of Laboratory Guidelines;

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

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

(v) 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;

(vi) 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;

(vii) Measurement Uncertainty (MU): The MU associated with the results obtained with the quantitative Confirmation Procedure shall be estimated in accordance with any applicable Agency procedures, Technical Document(s), Technical Letter(s), or Laboratory Guidelines. At a minimum, MU at levels close to the Threshold shall be addressed during the validation of the quantitative Confirmation Procedure.

(e) 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.

Rule 6307. Sample Analysis

(a) Laboratories shall analyze Samples collected by or on behalf of the Agency using any Analytical Testing menu directed by the Agency to detect the presence of Prohibited Substances or Prohibited Methods only (as defined in the Prohibited List).

(b) Covered Persons and their representatives are not permitted to be present for any aspect of Sample analysis or processing described in the Laboratory Standards, 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.

(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:

(1) Non-prohibited substances or methods that are included in the Agency monitoring program;

(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;

(3) Non-prohibited substances or methods requested as part of a Results Management process by an adjudicatory body or the Agency;

(4) Non-prohibited substances or methods requested by the Agency as part of its safety Protocol, Protocol of conduct or other regulations; or

(5) Additional analyses for quality assurance/quality improvement/method development or research purposes, in accordance with the requirements indicated in Rule 6320.

(d) At minimum, all Laboratories are required to implement all mandatory Analytical Testing Procedures, as determined by the Agency in compliance with any relevant Technical Document(s) and Technical Letter(s). Laboratories may implement additional methods for the analysis of particular Prohibited Substances or Prohibited Methods.

(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.

(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 Laboratory Standards and any applicable Agency procedures, 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.

(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 requested by the Agency, provided that the additional work is authorized by the Agency, conducted at the Laboratory's expense, and does not significantly affect the possibility to submit the Sample 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.

Rule 6308. Application of Initial Testing Procedures

(a) 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.

(b) The Initial Testing Procedure(s) shall fulfill the following requirements:

(1) The Initial Testing Procedure shall be Fit-for-Purpose;

(2) The Initial Testing Procedure shall be performed on Aliquot(s) taken from the container identified as the A Sample (and if the A Sample cannot be used for the Initial Testing Procedure(s), see Rule 6304);

(3) The Initial Testing Procedure shall be recorded, as part of the Sample (or Sample batch) record, each time it is conducted;

(4) All batches undergoing an Initial Testing Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis, unless otherwise specified by the Agency;

(5) The Initial Testing Procedures for Non-Threshold Substances shall include appropriate controls of representative substance(s) at or below the MRPL;

(6) The Initial Testing Procedures for Threshold Substances shall include appropriate controls close to the Threshold, unless otherwise specified by the Agency;

(7) Results from Initial Testing Procedures are not required to consider the associated MU, unless otherwise specified by the Agency; and

(8) The Laboratory shall establish criteria, based on its method validation and in accordance with its SOP, to evaluate results from an Initial Testing Procedure as a Presumptive Adverse Analytical Finding, which would trigger confirmation analyses.

Rule 6309. Application of Confirmation Procedures

(a) The objective of the Confirmation Procedure is to obtain a result, which supports or does not support the reporting of an Adverse Analytical Finding or Atypical Finding.

(b) 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 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.

(c) A result obtained in the Initial Testing Procedure 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.

(d) Irregularities in the Initial Testing Procedure(s) shall not invalidate an Adverse Analytical Finding, which is adequately established by a Confirmation Procedure.

(e) The Confirmation Procedure(s) shall fulfill the following requirements:

(1) The Confirmation Procedure(s) shall be Fit-for-Purpose, including the estimation of the MU associated with a quantitative Confirmation Procedure;

(2) The Confirmation Procedure(s) shall be recorded, as part of the Sample (or Sample batch) record, each time it is conducted;

(3) The Confirmation Procedure shall have equal or greater Selectivity than the Initial Testing Procedure and shall provide accurate quantification results (applicable to Threshold Substances). The Confirmation Procedure shall incorporate, when possible and adequate, a different Sample extraction protocol or a different analytical methodology, unless otherwise specified by the Agency; and

(4) All batches undergoing a Confirmation Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis.

Rule 6310. Confirmation Procedure Methods

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 and the Confirmation Procedure.

Rule 6311. A Confirmation Procedure

(a) Aliquots. The A Confirmation Procedure shall be performed using new Aliquot(s) taken from the container identified as the A Sample (and if the A Sample cannot be used for the Initial Testing Procedure(s), see Rule 6304). At this point, the link between the Sample external code, as shown in the Sample container, and the Laboratory internal Sample code shall be verified.

(b) Target Analyte(s). If the presence of more than one Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method is detected by the Initial Testing Procedure(s), the Laboratory shall confirm as many of the Presumptive Adverse Analytical Findings as reasonably possible (and such decision should consider the volumes available in the A and B Samples). The confirmation(s) shall prioritize the identification 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 by the Laboratory.

(c) Repetition of the A Confirmation Procedure. 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.

(d) A Confirmation Procedure for Non-Threshold Substances.

(1) For Non-Threshold Substances without Minimum Reporting Levels, Adverse Analytical Finding or 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 any relevant Technical Document(s) or Technical Letter(s) or in consideration of Laboratory Guidelines.

(2) For Non-Threshold Substances with Minimum Reporting Levels, Adverse Analytical 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), in compliance with any applicable Agency procedures or Technical Document, at an estimated concentration greater than the Minimum Reporting Level, unless there is valid justification for reporting the finding at levels below the Minimum Reporting Level (*e.g.,* if the analysis forms part of an ongoing investigation).

(e) A Confirmation Procedure for Threshold Substances.

(1) For Threshold Substances, Adverse Analytical Finding or Atypical Finding decisions for the A Sample shall be based on the confirmed identification (in accordance with any applicable Agency Procedures or Technical Document) 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 Decision Limit.

(2) Quantitative Confirmation Procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (*e.g.,* concentrations, chromatogram areas) or the ratio/score calculated from the mean(s) of the measured analytical values of 2 A Sample Aliquots, unless otherwise specified by the Agency. If there is not enough Sample volume to analyze 2 Aliquots, the maximum number of Aliquots that can be prepared shall be analyzed.

(3) 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%.

(4) For Threshold Substances, Markers of the ''biomarker profile'', or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Finding decisions 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 (*i.e.,* endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

Rule 6312. B Sample Procedure

(a) Testing Laboratory. If the B Sample procedure is to be performed, it will be performed in a different Laboratory from the A Sample analysis (with the choice of the Laboratory for the B Sample analysis determined exclusively by the Agency), except where the Agency considers it necessary for the same Laboratory to perform the B Sample procedure:

(1) due to reasonable concerns over Sample integrity or unstable analytes; or

(2) because no other Laboratory is available to perform the B Sample procedure within a reasonable period of time.

(b) Notification and timing of B Sample procedure.

(1) The B Sample procedure shall only be performed by the Laboratory upon request by the Agency.

(2) The Agency should inform the Laboratory, in writing, within 15 days following the reporting of an A Sample Adverse Analytical Finding by the Laboratory, whether the B Sample procedure shall be conducted. This includes situations when the Covered Person does not request the B Sample analysis or expressly or implicitly waives his or her right to the analysis of the B Sample, but the Agency decides that the B Sample procedure shall still be performed.

(3) If the B Sample procedure is to be performed, whether upon the request of the Covered Person in accordance with the Protocol or the Agency:

(i) as soon as reasonably practicable after the Agency so decides or the Covered Person so requests, the Agency should notify the Laboratory that performed the A Sample analysis, and the Laboratory that will perform the B Sample procedure, that the B Sample procedure will be performed;

(ii) within 5 days of receipt of the notice at Rule 6312(b)(3)(i), the Laboratory that performed the A Sample analysis should send the B Sample to the Laboratory that will perform the B Sample procedure; and

(iii) the Laboratory that will perform the B Sample procedure should perform the B Sample procedure as soon as reasonably practicable after receipt of the B Sample.

(4) The timing of the B Sample 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 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).

(c) Opening, Aliquoting and Resealing of B Sample.

(1) The B Sample procedure shall be performed using Aliquot(s) taken from the container defined as the B Sample (and if the B Sample cannot be used, see Rule 6304).

(2) If the B Sample container was not properly sealed 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 Sample procedure and will inform the Agency immediately to obtain instructions on how to proceed. In such cases, unless the entire case is dismissed, the B Sample procedure may have to be re-scheduled.

(3) The Laboratory shall ensure that the B Sample container is opened and Aliquots for the B Sample procedure are taken.

(4) The Laboratory shall also ensure that, after opening and taking Aliquots for the B Sample procedure, the B Sample is properly resealed.

(5) 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 occurred and that the B Sample was properly resealed.

(d) Target Analyte(s). If more than one Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method has been confirmed in the A Sample 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 shall be made in consultation with the Agency and documented.

(e) Repetition of the B Sample procedure. The Laboratory may repeat the B Sample procedure, 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 Sample 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.

(f) B confirmation with negative results. 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, one or more Laboratories shall conduct an internal investigation of the causes of the discrepancy between the A and B Sample results. Target Analytes (*e.g.,* parent compound, Metabolite(s), and Marker(s)) used to conclude the presence of a given Prohibited Substance or Use of a Prohibited Method may differ between the A and B Confirmation Procedures. This does not mean that the B confirmation results are negative, as long as the Analyte(s) targeted allows the unequivocal and conclusive identification of the Prohibited Substance or Prohibited Method in the B Sample.

(g) B Sample procedure for Non-Threshold Substances and exogenous Threshold Substances. For Non-Threshold Substances (including those with Minimum Reporting Levels) 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 any applicable Agency procedures or Technical Document) for the Adverse Analytical Finding to be valid, unless otherwise specified by the Agency. No quantification or estimation of concentrations of such Prohibited Substance, or its Metabolite(s) or Marker(s) is necessary.

(h) B Sample procedure for Threshold Substances.

(1) For Threshold Substances, Adverse Analytical Finding decisions for the B Sample results shall be based on the confirmed identification (in accordance with any applicable Agency procedures or Technical Document, applicable to B Sample 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 any applicable Agency procedures, 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 (plus any Measurement Uncertainty).

(2) Quantitative B Sample procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (*e.g.,* concentrations, chromatogram areas) or the ratio/score calculated from the mean(s) of the measured analytical values of two (2) B Sample Aliquots, unless otherwise specified by the Agency. If there is not enough Sample volume to analyze two (2) Aliquots, the maximum number of Aliquots that can be prepared shall be analyzed.

(3) For Threshold Substances or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Finding decisions 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 or its Metabolite(s) or Marker(s). Atypical Findings may result from non-conclusive determinations of the origin (*i.e.,* endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

Rule 6313. Further Analysis of Stored Samples

(a) 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).

(b) Selection of Samples and Laboratories for Further Analysis.

(1) Stored Samples may be selected for Further Analysis at the discretion of the Agency or the Authority.

(2) 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.

(3) 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.

(4) Further Analysis may also be performed on stored Samples that 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.

(5) Previously acquired Initial Testing Procedure 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 of 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.

(c) Analytical Testing Procedures for Further Analysis of stored Samples.

(1) Further Analysis of stored Samples shall be performed under the Laboratory Standards, Technical Documents, and Technical Letters in effect at the time the Further Analysis is performed. Any

Laboratory Guidelines may also be referenced.

(2) Further Analysis of stored Samples includes, notably, but without limitation, the application of newly developed or more sensitive Analytical Testing Procedures or the analysis of new target Analytes of Prohibited Substance(s) or Prohibited Method(s) (*e.g.,* Metabolite(s) or Marker(s)), which were not known or not included in the initial Analytical Testing of the Sample.

(3) Depending on the circumstances, and to ensure an effective and targeted use of the available Sample volume, priorities may be set, 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).

(d) Further Analysis of stored Samples process.

(1) Use of the A Sample. 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.

(i) If the Laboratory has been instructed to perform only the 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.

(ii) When a Confirmation Procedure is performed on the A Sample and an Adverse Analytical Finding is reported on this basis, the B Sample procedure shall be applicable (as per Rule 6316).

(2) Use of the split B Sample. 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 2 fractions, in accordance with Rule 6304.

(i) In the event an Adverse Analytical Finding is notified based on the results of a B Sample procedure of the first fraction of the B Sample, the second split fraction of the B Sample shall be deemed as the B Sample. Since the first split fraction of the B Sample is considered as an A Sample, analysis of Aliquots taken from this Sample may include the performance of Initial Testing Procedure(s) and A Confirmation Procedures or A Confirmation Procedures only (if the Initial Testing Procedure(s) was/were already performed using the A Sample).

(ii) If applicable, a B confirmation shall be decided and performed in accordance with Rule 6316.

(e) Alternative biological matrices. 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, blood (including whole blood, plasma or serum), or hair.

Rule 6314. Assuring the Validity of Analytical Results

(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 shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.

(b) All quality control procedures shall be documented by the Laboratory. The range of quality control activities include, but are not limited to:

(1) Use of appropriate quality control samples (QCs).

(i) Appropriate positive and negative QCs shall be included in every analytical run both for the Initial Testing Procedure(s) and B Sample procedure(s), unless otherwise specified by the Agency.

(ii) Appropriate internal standard(s) shall be used for chromatographic methods.

(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; +/−MU95%), shall be regularly used to monitor method performance and inter-batch variability (when applicable).

(2) Implementation of an Internal Quality Assurance Scheme (iQAS).

(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.

(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.

(iii) The Laboratory shall have a dedicated SOP for the iQAS program which incorporates a detailed procedure for the planning, preparation (blind or double-blind), introduction of the iQAS samples, and management of the iQAS results (*i.e.,* reviewing and follow-up of nonconformities).

(3) Mandatory participation in the Agency EQAS.

(4) Implementation of internal audits.

(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, and specification of their auditing activities, as well as for management of the internal audit conclusions (*i.e.,* reviewing and follow-up of nonconformities).

(ii) Internal audit responsibilities may be shared amongst personnel provided that any Laboratory staff member does not audit his or her own area.

(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.

(5) Implementation of external audits. 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.

Rule 6315. Results Management

(a) Review of results. The Laboratory shall conduct a minimum of one independent review of all Initial Testing Procedure raw data and results. The review process shall be recorded.

(b) A minimum of 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.

(c) Second opinion. The Laboratory may request a second opinion from another Laboratory, selected by, and upon approval of, the Agency, before reporting an Adverse Analytical Finding or Atypical Finding. Such requests for second opinions may be required by specific Technical Document(s) or Technical Letter(s), required by the Agency from certain Laboratories 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. The Laboratory that performed the analysis is responsible for the result and for issuing the final test report.

(d) Laboratory review of Adverse Analytical Findings and Atypical Findings. At a minimum, the review of Adverse Analytical Findings and Atypical Findings shall include:

(1) Documentation linking the Sample (as specified in the Sample collection documentation) to the Laboratory Internal Chain of Custody documentation;

(2) Laboratory Internal Chain of Custody documentation;

(3) Initial Testing Procedure(s) and Confirmation Procedure(s) analytical data and calculations;

(4) Quality control data;

(5) Completeness of technical and analytical documentation supporting the reported findings;

(6) Compliance of test data with the Analytical Testing Procedure's validation results (*e.g.,* MU); and

(7) Assessment of the existence of significant data or information that would cast doubt on or refute the Laboratory findings.

(e) 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.

(f) Traceability of results and documentation. 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 Finding or Atypical Finding, the record shall include the data necessary to support the conclusions reported.

(1) Each step of Analytical Testing shall be traceable to the staff member who performed that step;

(2) Significant deviation from a written SOP shall be recorded;

(3) Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record;

(4) Requests for information by the Agency to a Laboratory shall be made in writing;

(5) 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.

(g) Confidentiality of the Analytical Data and Covered Person or Covered Horse's identity.

(1) The Laboratory shall not make any attempt to identify a Covered Person linked to, or the Covered Horse that has provided, a Sample.

(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.

(3) Secure emails or documents shall be used for reporting or discussion of Adverse Analytical Findings or Atypical Findings if the Covered Person or Covered Horse can be identified or if any information regarding the identity of the Covered Person or Covered Horse is included.

Rule 6316. Reporting Test Results

(a) Reporting times (including confirmatory analysis).

The Laboratory should report all A Sample results to the Agency in a form designated by the Agency within 10 business days of receipt by the Laboratory of the Sample. The reporting time may be altered by agreement between the Laboratory and the Agency. The Agency shall be promptly informed of any delay in the reporting of A Sample results.

(b) Reporting requirements.

(1) The Laboratory shall record the test result for each individual Sample to, and in a form designated by, the Agency.

(2) The Laboratory shall report test results to the Agency in a form designated by the Agency. When reporting test results, the Laboratory shall include the following, in addition to the mandatory information required by the Agency, in any relevant Technical Document(s) or Technical Letter(s), and in the ISO/IEC 17025 standard:

(i) The specific gravity of the Sample, if applicable (Initial Testing Procedure and A and B Confirmation Procedures);

(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);

(iii) Specific tests performed, in addition to the Laboratory's routine Analytical Testing menu (*e.g.,* EPO, bisphosphonates, hGH); and

(iv) Any irregularities noted on Samples.

(c) 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 provide any information requested by the Agency in relation to the Monitoring Program (Protocol).

(d) The Laboratory shall qualify the result(s) of the analysis in the Agency's test report as:

(1) Adverse Analytical Finding;

(2) Atypical Finding;

(3) Negative Finding; or

(4) Not Analyzed.

(e) Any Sample received at the Laboratory and not subject to Analytical Testing for a valid, documented reason (as instructed or agreed to by the Agency), such as Sample irregularities or intermediate Samples of a Sample Collection Session, shall be dealt with in accordance with ISO/IEC 17025.

(f) Test report for Non-Threshold Substances.

(1) A Sample test report.

(i) The Laboratory is not required to report concentrations for Non-Threshold Substances. The Laboratory shall report the actual Prohibited Substance(s) or its Metabolite(s), or Marker(s) of the Use of Prohibited Substance(s) or Prohibited Method(s) present in the Sample and in accordance with any reporting requirements established by the Agency or in any applicable Technical Document.

(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 shall indicate the estimated concentration while making it clear to the Agency that the concentration was obtained by an Analytical Testing Procedure that has not been validated for quantitative purposes.

(2) B Sample test report. 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 any reporting requirements established by the Agency or in relevant 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).

(g) Test report for Threshold Substances. 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, ratio, or score of measured analytical values greater than the Threshold, or that the Prohibited Substance(s) or its Metabolite(s) or Marker(s) is of exogenous origin.

Rule 6317. Control of Nonconformities in Analytical Testing

(a) The Laboratory shall have policies and procedures that shall be implemented when any aspect of its Analytical Testing does not comply with then-current requirements.

(b) Any nonconformities in Analytical Testing shall be recorded and kept as part of the documentation of the Sample(s) involved.

(c) When conducting a corrective action investigation, the Laboratory shall perform and record a thorough Root Cause Analysis of the nonconformity.

Rule 6318. Complaints

Complaints shall be handled in accordance with ISO/IEC 17025.

Rule 6319. Storage of Samples

(a) Storage of urine Samples. 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 unless and until notified in writing by the Agency that such records may be destroyed.

(1) Urine Sample(s) without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the A and B urine Sample(s) without an Adverse Analytical Finding or Atypical Finding for a minimum of 3 months after reporting the final analytical result to the Agency, and they 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. The Laboratory may charge storage costs to the Agency, as applicable, for the storage of Samples for periods longer than the stated minimum storage times. However, the Laboratory may store Samples beyond the applicable minimum storage times at their own discretion and expense. In such cases, the Laboratory shall inform the Agency in writing. Any Further Analysis on these Samples will require the approval of the Agency. The maximum storage period is 10 years after the Sample collection date.

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

(3) Urine Sample(s) with an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the A and B urine Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of 6 months after reporting the final analytical result for the A or the B Sample, as applicable to, the Agency and shall not dispose of any such Samples without approval by the Agency.

(4) 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 Rule 6319) 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.

(b) Storage of blood Samples.

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

(i) 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.

(ii) Serum/plasma A and B Samples without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the serum/plasma A and B Samples without an Adverse Analytical Finding or Atypical Finding for a minimum of 3 months after reporting the final analytical result to the Agency, unless long-term storage of the Sample(s) has been requested by the Agency or the Agency requests the Laboratory retain the Sample for a longer period.

(iii) Unless otherwise requested by the Agency, serum/plasma Samples analyzed only for TCO2 and without an Adverse Analytical Finding or Atypical Finding, shall be retained unless and until the corresponding Post-Race Sample is analyzed and no Adverse Analytical Finding or Atypical Finding is reported (*i.e.,* if the Post-Race Sample is analyzed and an Adverse Analytical Finding or Atypical Finding is reported, then the Agency may consider or conduct Further Analysis on the TCO2 Sample).

(iv) Serum/plasma Samples with irregularities: The Laboratory shall retain the serum/plasma Samples with irregularities for a minimum of 3 months after reporting the final analytical result to the Agency, or for a longer period if directed by the Agency.

(v) Plasma/serum A and B Sample(s) with an Adverse Analytical Finding or 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 6 months after reporting the final analytical result (for the A or the B Sample, as applicable) to the Agency and shall not dispose of any such Samples without approval by the Agency. If the B Sample Confirmation Procedure is not performed, the Laboratory may dispose of both the A and B whole blood Samples 3 months after reporting the A Sample analytical result. However, if the B Sample Confirmation Procedure is performed, then the Laboratory shall retain both the A and B whole blood Sample(s) for a minimum of 3 months after reporting the B Sample analytical result.

(vi) 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 Rule 6319) 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.

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

(i) Whole blood A and B Samples without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the whole blood Samples without an Adverse Analytical Finding or Atypical Finding for a minimum of 1 month after reporting the final analytical result to the Agency, unless long-term storage of the Sample(s) has been requested by the Agency or the Agency requests the Laboratory retain the Sample for a longer period.

(ii) Whole blood Samples with irregularities: The Laboratory shall

retain the whole blood Samples with irregularities for a minimum of 1 month after reporting the final analytical results to the Agency, or for a longer period as requested by the Agency.

(iii) Whole blood A and B Sample(s) with an Adverse Analytical Finding or 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 3 months after reporting the final analytical result (for the A or the B Sample, as applicable) to the Agency and shall not dispose of such Samples without approval by the Agency.

(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 Rule 6319) 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, and shall not dispose of such Samples without approval by the Agency.

(c) Storage of hair Samples. All hair Samples retained for storage in the Laboratory shall be stored for as long as requested by the Agency in a secure location under continuous chain of custody.

(d) Storage of other Samples. All other Samples shall be stored for as long as requested by the Agency 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.

(e) Long-term storage of Samples.

(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 Rules 6313 and 6319.

(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. The Agency shall retain the Sample collection records pertaining to all stored Samples for the duration of Sample storage.

(3) Laboratories as Sample custodians:

(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.

(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.

(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. For example, Sample(s) may be resealed with new resealing systems (*e.g.,* new bottlecaps) produced by the manufacturer of an appropriate Sample collection equipment that replicates the security and Tamper Evident functionality of the original seal. The resealing system of shipped A Sample(s) shall be Tamper Evident.

(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.

(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 Finding or other result upon which the Anti-Doping Rule Violation is based.

(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 Rule 6313.

(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.

(4) The Agency as Sample custodians:

(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.

(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.

(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, 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 Rule 6313.

(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.

(4) The Agency as Sample custodians:

(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.

(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.

(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, 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 Rule 6313.

(f) For the purposes of this rule, ''storage'' refers to A and B Samples stored in Sample collection containers (urine collection bottles, blood collection tubes) and should not be confused with access to Aliquots, which should be accessible to analysts for the performance of Analytical Testing Procedures. However, minimum and maximum retention times apply to any

Aliquot(s) of a Sample that remains after completion of the Analytical Testing.

Rule 6320. Secondary Use or Disposal of Samples and Aliquots

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

(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:

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

(2) Secondary use of Samples and Aliquots for research and quality assurance. Samples and Aliquots shall be anonymized to ensure that any subsequent results cannot be traced back to a particular Covered Person or Covered Horse. Only after anonymization, may a Sample or Aliquot be used for:

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

(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.

(c) The use of Samples and Aliquots for the purposes of this Rule 6320 is subject to the following conditions:

(1) The Laboratory must respect the Protocol and the 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;

(2) The Laboratory must not make any attempt to re-identify a Covered Person or Covered Horse from Samples or Aliquots used for the purposes of this Rule 6320 or data arising from any research or quality assurance analysis;

(3) The Laboratory must consult the applicable State and Federal regulations, guidance, or authorities to determine whether a study shall be considered as falling under Rule 6320(c)(1) or (2) (if the Laboratory is unsure whether a study can proceed without consent after consulting the foregoing sources, the Laboratory shall consult with the Agency to determine whether it can proceed); and

(4) In the event the Laboratory wishes to transfer Sample(s) or Aliquots to be used for the purposes of this Rule 6320 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 a study pursuant to Rule 6320(c)(1), the Laboratory shall subject the receiving party to the conditions described in this Rule 6320 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.

6400. Evaluation of Laboratory EQAS

Rule 6410. Penalties

(a) The Agency shall inform a Laboratory in writing about the imposition of penalties, corrective action, or other follow-up measures.

(b) Technical or methodological error. 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.

(c) Clerical/Administrative error. 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. For the purposes of Laboratory performance evaluation, clerical/administrative errors are defined as those incidental, non-systematic errors of no technical or methodological origin, which have been committed by the Laboratory during the performance of Analytical Testing (*e.g.,* a typographical error when manually recording an analytical result). The Laboratory shall bear no responsibility for clerical/administrative errors reflected in the Laboratory documentation made by the Agency.

Rule 6420. Corrective Action Reports

(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.

(b) A Corrective Action Report related, for example, to nonconformities detected during the Agency Laboratory assessments, or to procedural or reporting nonconformities with the Laboratory Standards, Technical Documents or Technical Letters, or unsatisfactory performance in the analysis of EQAS samples (not related to a false Adverse Analytical Finding or false Negative Finding), shall be submitted to the Agency within 30 days of the Agency's notification to the Laboratory.

(c) Unless otherwise agreed with the Agency, the corrective and preventive action(s) reported to and approved by the Agency shall be implemented immediately in the routine operations of the Laboratory.

(d) 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.

(e) Satisfactory Corrective Action Report. A Corrective Action Report will be considered as satisfactory when it meets the following criteria, as determined by the Agency:

(1) 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);

(2) Leads to the documented implementation of effective corrective action(s) to solve the problem; and

(3) Leads to the documented implementation of appropriate preventive actions, if applicable, to minimize the risk of recurrence of the problem.

(f) 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.

(g) Unsatisfactory Corrective Action Report. If the Laboratory's Corrective Action Report is considered unsatisfactory by the Agency, the Agency should provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within 7 days, or as otherwise agreed by the Agency.

(h) 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.

Rule 6430. Laboratory Self-Reporting

The Laboratory must identify and report all errors in Sample analysis resulting in a false Adverse Analytical

Finding or a false Negative Finding. Self-reporting will be taken into consideration by the Agency in determining whether or not to impose a penalty (or what that penalty will be).

Rule 6440. Evaluation of EQAS Results

(a) Satisfactory EQAS performance in a single EQAS round and over a consecutive 12-month period is necessary for maintaining HEAL accreditation. An EQAS round is a distribution of EQAS sample(s) to the Laboratories and the probationary laboratories for Analytical Testing (as defined by the Agency). The 12-month period is defined as the most recent consecutive 12-month interval starting either from the date that the Laboratory or the probationary laboratory reported the nonconforming result (EQAS or routine Analytical Testing, as applicable) to, and in a form designated by, the Agency, or from the date that the Laboratory or probationary laboratory is informed, in writing, of nonconformity by the Agency, whichever is more favorable to the Laboratory or the probationary laboratory.

(b) 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. 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. Some Analytical Testing Procedures are not eligible for a flexible scope of ISO/IEC 17025 accreditation and require specific Agency approval before the Laboratory can apply the procedure to the analysis of Samples. Agency approval will be based on its assessment of the Fitness-for-Purpose of the Analytical Testing Procedure, method validation by the Laboratory, and the successful Laboratory participation in an inter-laboratory collaborative study or the Agency EQAS round. The Agency will communicate which Analytical Testing Procedures fall into this category to the Laboratories and to the Accreditation Bodies.

Rule 6441. EQAS Samples Containing Non-Threshold Substances

(a) 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.

(b) The results for any Non-Threshold Substance or its Metabolite(s) or Marker(s) at concentrations greater than (>) the MRPL (or exceeding 120% of the Minimum Reporting Level, when applicable) shall be evaluated.

(c) The results for any Non-Threshold Substance or its Metabolite(s) 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.

(d) If the results for any Non-Threshold Substance or its Metabolite(s) or Marker(s) are at concentrations below (<) 50% of the applicable MRPL in an EQAS sample, the Laboratory shall report its finding(s) if the analyses are compliant with its validation data, SOPs, the Laboratory Standards, and any applicable Technical Document. Laboratories unable to report such substance(s) are encouraged, on receipt of the EQAS report, to consider re-assessment of their Analytical Testing Procedure.

Rule 6442. EQAS Samples Containing Threshold Substances

(a) 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).

(b) A Laboratory is to achieve a satisfactory statistical evaluation of quantitative results reported based on the mean of 2 replicate determinations. The overall evaluation of the quantitative performance is based on the criteria indicated in any relevant Technical Document or Technical Letter, or the Laboratory Guidelines.

(c) 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 decimal place) for the Laboratory's quantitative result is <3.0.

(d) Unsatisfactory quantitative result for Threshold Substances (absolute z-score ≥ 3.0). The Laboratory shall provide the Agency with a Corrective Action Report for an unsatisfactory quantitative result. The z-score is calculated according to the formula $[z=(\bar{y}-\hat{y})/\delta]$, where $\bar{y}$ is the mean value of the Laboratory's replicate determinations; $\hat{y}$ is the assigned value (reference, nominal or consensus value, as applicable); δ is the target standard deviation (*e.g.,* uc_Max or robust Reproducibility sR of results from all participant Laboratories). The z-score is truncated to one decimal place.

(e) Questionable quantitative result (absolute z-score >2.0 and <3.0). 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.

(f) EQAS evaluation of Laboratory performance. Where an EQAS result is reported incorrectly, the Laboratory shall provide the Agency with a Corrective Action Report.

(g) Double-blind, blind EQAS and educational EQAS samples. Failure to report accurately, in accordance with criteria, 3 blind or double-blind EQAS, or educational EQAS results within a continuous twelve 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.

Rule 6443. False Adverse Analytical Finding or False Negative Finding

(a) If the Laboratory discovers that it reported a false Adverse Analytical Finding or false Negative Finding, the Laboratory shall inform the Agency immediately.

(b) When the false Adverse Analytical Finding or 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.

(c) The Agency, considering the nature of the error that caused the false Adverse Analytical Finding or 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 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 12 months (or during a period otherwise determined by the Agency) within 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. The retrospective review of the analytical results and re-analysis of previous relevant Samples reported as Adverse Analytical Finding(s) shall be performed with the objective of determining whether any other related (*i.e.,* produced by the same root cause(s)) false Adverse Analytical Finding(s) have been reported by the Laboratory. The discovery of additional false Adverse Analytical Finding(s) shall lead to the implementation of corrective measures and shall be communicated to the Agency.

(1) During the period of suspension, the Laboratory shall follow the instructions provided in Rule 6561 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 Rules 6560 and 6302.

(2) 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.

(3) 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.

Rule 6450. Further Procedural Evaluations

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. Rule 6450 does not apply to the evaluation of Corrective Action Reports for false Adverse Analytical Findings or false Negative Findings, which are covered in Rule 6443.

Rule 6460. Overall Laboratory Evaluation

(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.

(b) 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 6 months or until such a time when the Laboratory can satisfactorily correct all the issues identified (at the Agency's discretion). If the Laboratory under suspension fails to satisfy performance criteria during an extended period of suspension (beyond the initial 6 months), then the Agency may Revoke the Laboratory's accreditation.

(c) Laboratories under an Analytical Testing Restriction remain operational (except for any activities under the Analytical Testing Restriction) and, therefore, are evaluated during the Analytical Testing Restriction as any other, fully operational Laboratory.

Rule 6470. Probationary Period and Probationary Laboratory Evaluation

(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.

(b) The Agency will evaluate probationary laboratory EQAS performance.

(c) 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.

(d) Any false Adverse Analytical Finding or false Negative Finding of a technical or methodological nature reported automatically suspends a probationary laboratory from further consideration for HEAL accreditation.

(e) 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 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.

(f) 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 or to require that the laboratory be reassessed, at the expense of the laboratory. Laboratories re-entering the probationary EQAS shall be considered candidate laboratories and are required to provide the applicable accreditation fee and documentation to the Agency.

Rule 6480. Removal of Samples by the Agency for Analysis or Further Analysis

(a) 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 any purpose described in the Protocol. The Agency shall retain the right to request analysis or Further Analysis, at its expense, as permitted by the Protocol.

(b) 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).

(c) The Agency may also require that the Laboratory transfer the Samples to other Laboratories selected by the Agency. 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).

(d) Where for any reason (except where Rule 6312 applies), a Laboratory transfers a Sample to another Laboratory, the first Laboratory shall

send the Sample within 5 business days following receipt by the first Laboratory of the request to transfer the Sample.

(e) In connection with its monitoring of Laboratory performance, the Agency may direct Further Analysis of a Sample which has resulted in an Anti-Doping Rule Violation without consent of the Covered Person or approval from an adjudication body, as provided in the Protocol.

Rule 6490. Removal of Samples by the Agency for Laboratory Quality Assessment

The Agency may also direct the re-analysis of anonymized Samples, which have met the conditions described in Rule 6320, 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.

6500. Withdrawal of Heal Accreditation

Rule 6510. Withdrawal of HEAL Accreditation

(a) A Laboratory's HEAL accreditation may be suspended, Revoked, or subject to an Analytical Testing Restriction, whenever the Laboratory fails to comply with the Laboratory Standards, Technical Documents, 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.

(b) The imposition of an Analytical Testing Restriction or the suspension of a Laboratory's HEAL accreditation shall 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.

(c) The Agency may suspend a Laboratory's HEAL accreditation or impose an Analytical Testing Restriction against a Laboratory if the Agency identifies noncompliance with the Laboratory Standards, Technical Documents, or Technical Letters based on the Laboratory's performance during the EQAS or during routine Analytical Testing.

(d) The Laboratory may not challenge the penalty imposed by the Agency.

Rule 6520. Noncompliance With the Laboratory Standards

(a) Noncompliance with the Laboratory Standards that may lead to an Analytical Testing Restriction, suspension or Revocation of HEAL accreditation, or other follow-up measures include, but are not limited to:

(1) Suspension or withdrawal of ISO/IEC 17025 accreditation;

(2) Failure to establish or maintain administrative and operational independence as described in paragraph (b)(7) of Rule 6110;

(3) Failure to analyze the minimum number of Samples indicated in paragraph (i) of Rule 6130 (except where the Agency fails to send the minimum annual number of Samples to the Laboratory);

(4) Reporting of false Adverse Analytical Findings or false Negative Findings;

(5) Failure to implement a Technical Document or Technical Letter by the effective date without prior approval of the Agency;

(6) Failure to comply with any of the requirements or standards listed in the Laboratory Standards, Technical Documents or Technical Letters;

(7) Noncompliance with results reporting timelines in Rule 6316;

(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;

(9) Failure to take appropriate corrective action for Laboratory Standards, Technical Document(s), or Technical Letter(s) noncompliance(s) identified from the Agency Laboratory assessment(s);

(10) Analysis of Samples from the Agency in violation of a suspension or Analytical Testing Restriction decision;

(11) Failure to cooperate with the Agency in providing documentation or other requested information;

(12) Noncompliance with the Code of Ethics; or

(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.

(b) Laboratory staff or management issues which may lead to an Analytical Testing Restriction, suspension or Revocation of HEAL accreditation, or other follow-up measures include, but are not limited to:

(1) Major changes in senior Laboratory management positions (*e.g.,* Laboratory Director, Quality Manager) without proper and timely notification (usually within 30 days) to the Agency;

(2) Failure to appoint a permanent Laboratory Director or other senior management positions (*e.g.,* Quality Manager) within a reasonable time period;

(3) Failure to guarantee the competence or proper training of scientific staff including, for example, the qualification of analysts as Certifying Scientists and Laboratory Supervisory Personnel;

(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;

(5) Conviction of any key personnel for any criminal offence that is determined by the Agency to impact the operations of the Laboratory;

(6) Loss of sufficient Laboratory support and resources that affects, as determined by the Agency, the quality or viability of the Laboratory; or

(7) Failure to cooperate in any Agency inquiry in relation to the activities of the Laboratory.

Rule 6530. Notification of Penalty Decision

The Agency shall provide the Laboratory with written notice of its decision regarding penalties. This notice shall state the following:

(a) That the Laboratory's HEAL accreditation has been maintained (including warnings, if applicable); or

(b) 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:

(1) the reason(s) for suspension, Revocation, or the imposition of an Analytical Testing Restriction;

(2) the terms of the suspension, Revocation, or Analytical Testing Restriction;

(3) the period of suspension or Analytical Testing Restriction, if applicable; and

(4) Any corrective actions or other follow-up requirements imposed upon the Laboratory by the Agency.

Rule 6540. Effective Date and Appeals

(a) A Revocation, suspension, or Analytical Testing Restriction is effective immediately upon receipt of notification of the Agency's decision.

(b) The Agency's decision is not subject to appeal.

Rule 6550. Public Notice

(a) The Agency shall publicly announce a change in a Laboratory's accreditation status (including, if appropriate, any Analytical Testing Restriction) on its website as soon as practicable after the Laboratory is notified by the Agency of its decision.

(b) The Agency's website shall be updated regarding a Laboratory's accreditation status when:

(1) the Laboratory's HEAL accreditation is reinstated following a suspension;

(2) an Analytical Testing Restriction is removed (if appropriate); or

(3) a Laboratory whose accreditation has previously been Revoked is re-accredited.

Rule 6560. Consequences of an Analytical Testing Restriction

(a) 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 requested by the Agency for 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.

(b) 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.

(c) The Laboratory under an Analytical Testing Restriction shall contact the Agency to arrange for the transfer of the relevant Samples to subcontracted Laboratory(-ies), selected by the Agency, within 30 days of being notified of the Analytical Testing Restriction decision. All associated costs shall be borne by the Laboratory under Analytical Testing Restriction. 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, 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:

(1) Samples which had been previously reported as an Adverse Analytical Finding (as requested by the Agency);

(2) Samples which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Analytical Testing Restriction decision;

(3) 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, and Samples that are the subject of other Confirmation Procedures;

(4) 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, and Samples which were undergoing A or B Confirmation Procedures at the time of the imposition of the Analytical Testing Restriction;

(5) 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 transferred to another Laboratory(-ies) selected by the Agency for the A Confirmation Procedure to be performed again and for the performance of the B Confirmation Procedure, if applicable; and

(6) 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) selected by the Agency for Further Analysis, as determined by the Agency. These re-analyses may be applied to the class of Prohibited Substances or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by the Agency.

Rule 6561. Consequences of Suspension

(a) A Laboratory whose HEAL accreditation has been suspended is ineligible to perform Analytical Testing of Samples.

(b) Suspension for violation of the Code of Ethics. 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 all Samples (both the A and B Samples) in the Laboratory's custody to other Laboratory(-ies) selected by the Agency.

(c) Suspension for reporting of false Adverse Analytical Finding(s). 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) selected by the Agency for the performance of the A and, if needed, the B Confirmation Procedures, unless otherwise instructed by the Agency:

(1) Samples which had been previously reported as an Adverse Analytical Finding for the same class of Prohibited Substances or Prohibited Methods when applying the same Confirmation Procedure (as requested by the Agency);

(2) 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, and Samples that are the subject of other Confirmation Procedures;

(3) Samples which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the suspension;

(4) 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) selected by the Agency);

(5) Samples for which A or B Confirmation Procedures had been completed, but results of the analysis had not been reported by the suspension date, and Samples which were undergoing A or B Confirmation Procedures at the time of the suspension; and

(6) Samples which had been reported as Adverse Analytical Findings based on the A Confirmation Procedure prior to the suspension.

(d) Suspension for other reasons. 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 respect to the Samples in the Laboratory's custody, unless otherwise instructed by the Agency:

(1) 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 3 months or have been placed in long-term storage upon request by the Agency 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 codes.

(2) 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) selected by the Agency for Further Analysis, as determined by the Agency. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the Analytical Testing menu requested by the Agency or be limited to the class of Prohibited Substances or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by the Agency.

(3) Samples for which Initial Testing Procedures had been completed, but results had not been reported at the time of the suspension:

(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 transferred to another Laboratory(-ies) selected by the Agency for the performance of the A and, if needed, the B Confirmation Procedures.

(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) selected by the Agency 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 Analytical Testing menu requested by the Agency or be limited to the class of Prohibited Substances or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding, as determined by the Agency.

(iii) If the reason for the suspension was not related to the reporting of false Negative Findings and the Initial Testing Procedures 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 codes.

(4) Samples which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the suspension:

(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 Procedures are completed. If the Initial Testing Procedures 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 codes.

(ii) However, if the Initial Testing Procedure produced a Presumptive Adverse Analytical Finding, both the A and B Samples shall be transferred to another Laboratory(-ies) selected by the Agency for the performance of the A and, if needed, the B Confirmation Procedures.

(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 transferred to another Laboratory(-ies) selected by the Agency for the performance of the A and, if needed, the B Confirmation Procedures.

(5) Samples which had been received at the Laboratory but had not been opened yet at the time of the suspension: 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) selected by the Agency for Analytical Testing.

(6) Samples for which A or B Confirmation Procedures had been completed, but results of analysis had not been reported by the suspension date, and Samples which were undergoing A or B Confirmation Procedures at the time of the suspension: both the A and B Samples shall be transferred to another Laboratory(-ies) selected by the Agency for the repetition of the A and, if applicable, the B Confirmation Procedures.

(7) Samples which had been reported as an Adverse Analytical Finding based on the A Confirmation Procedure prior to the suspension:

(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 transferred to another Laboratory(-ies) selected by the Agency for the A Confirmation Procedure to be performed again and for the performance of the B Confirmation Procedure, if applicable.

(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 or perform a Laboratory assessment, at any time and at the expense of the Laboratory, in order to evaluate the Laboratory's status.

Rule 6562. Revocation

(a) 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) selected by the Agency.

(b) A laboratory whose HEAL accreditation has been revoked shall arrange the transfer of Samples in the laboratory's custody to a Laboratory(-ies) selected by the Agency, respectively, within 30 days of being notified of the decision revoking its HEAL accreditation. In such circumstances, the Samples to be transferred shall be selected by the Agency. The laboratory transferring the Samples shall inform the Agency and provide the relevant Sample codes and the selected 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.

(c) 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 paragraphs (a) through (d) of Rule 6319, 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) selected by the Agency.

Rule 6563. Reinstatement of Suspended Accreditation or Lifting of Analytical Testing Restriction

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 in its sole discretion, 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.

Rule 6564. Extension of Suspension or Analytical Testing Restriction

(a) If a Laboratory whose HEAL accreditation has been suspended or which has been the subject of an Analytical Testing Restriction has not satisfactorily corrected the Laboratory Standards, Technical Document(s), or Technical Letter(s) noncompliance(s) that resulted in the suspension or Analytical Testing Restriction, or if the Agency identifies any additional Laboratory Standards, Technical Document(s) 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 the 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 6 months, if the Laboratory provides valid 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).

(b) 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.

(c) 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.

(d) 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 Laboratory Standards, Technical Document(s), or Technical Letter(s) noncompliance(s) have been corrected, the Laboratory's accreditation may be re-instated or the Analytical Testing Restriction may be lifted by decision of the Agency in its sole discretion.

(e) 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.

(f) The Agency will notify the Laboratory of its decision to revoke the Laboratory's HEAL accreditation in accordance with Rule 6530.

Rule 6565. Revoked Accreditation

(a) 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 Rule 6110.

(b) 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 Rule 6110 to expedite the entry of the laboratory into, 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.

Rule 6570. Voluntary Cessation of Laboratory Operations

(a) 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 Laboratory Standards noncompliance(s) and not having been subject to an Analytical Testing Restriction or suspension or Revocation of its HEAL accreditation.

(b) 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 made to cease its operations and, in any event, no later than 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) selected by the Agency, in accordance with Rule 6561 (temporary closure) or Rule 6562 (permanent closure).

(c) 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 6 months, with one possible extension of up to 6 months (as determined by the Agency). If the Laboratory is unable to resume its Analytical Testing operations within a 12-month period, the Agency shall revoke the Laboratory's accreditation, unless otherwise approved by the Agency.

(d) 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 by the Agency to receive the Samples.

6600. Code of Ethics for Laboratories and Research and Development Activity Requirements

Rule 6610. Code of Ethics for Laboratories

(a) Compliance. Directors of Laboratories, their delegates and all Laboratory staff shall respect and comply with the Laboratory Standards and the Protocol. Laboratories and all of their staff shall maintain the confidentiality of all of data, items and information received in connection with Doping Control and Medication Control, including, but not limited to, Samples, Testing documentation, and communications with the Agency.

(b) Research in support of Doping Control.

(1) 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.

(2) 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.

(3) Laboratories are expected to conduct research on Equine (and other animal species) subjects.

(4) Laboratories shall follow institutional animal care and use guidelines and requirements regarding the use of animal subjects in research.

(5) Covered Horses who may undergo Doping Control Testing shall not be the subjects of drug administration studies that include Prohibited Substances or Prohibited Methods.

(c) Controlled substances. Laboratories are expected to comply with the relevant and applicable local, State and Federal laws regarding the handling, storage and discarding of controlled or illegal substances.

(d) Analysis. Laboratories shall not engage in any analysis or activity that undermines or is detrimental to the purposes of the Act.

(e) Analytical Testing for other anti-doping organizations. Laboratories shall accept Samples for Analytical Testing only if all the following conditions have been met:

(1) The Sample matrix is of the proper type (*e.g.,* blood, urine, hair or other Samples) for the requested analyses;

(2) The Samples have been collected, sealed and transported to the Laboratory in accordance with procedures equivalent to the Testing and Investigations Standards; and

(3) 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 Rule 6307.

(f) Analytical Testing for Covered Persons or those acting on their behalf. Laboratories shall not accept Samples directly from individual Covered Persons or from individuals or organizations acting on his or her behalf (unless approved in writing and in advance by the Agency and on the condition that Samples will be treated as Samples under the Protocol). Proceedings may be brought against the relevant Covered Person(s) if evidence of an Anti-Doping Rule Violation or a Controlled Medication Rule Violation emerges from such Sample analysis.

(g) Other analytical activities.

(1) Laboratories shall not provide analytical services in a Doping Control adjudication, unless specifically requested by the Agency or an adjudication body as part of a Results Management process.

(2) Laboratories shall not engage in analyzing commercial material or preparations (*e.g.,* dietary or herbal supplements), unless:

(i) Specifically requested by the Agency or an adjudication body as part of a Results Management process;

(ii) If done as part of a legitimate anti-doping research program, as determined by the Agency; or

(iii) If a request is made by a Covered Person or his or her representative, a Laboratory may conduct the analysis if agreed in advance and in writing 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).

(3) Laboratories shall not provide results, documentation or advice that, in any way, could be used as an endorsement of products or services.

(4) 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. Laboratory test reports or other documentation or correspondence related to these other analytical activities shall not declare or represent that any such testing is covered under the Laboratory's Agency-accredited status.

(h) Sharing of knowledge.

(1) When information on new doping substance(s), method(s), or practice(s) is known to a Laboratory, such information shall be shared with the Agency within 60 days. When possible, 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.

(2) 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.

(i) Duty to preserve the integrity of the Program contemplated in the Act and to avoid any detrimental conduct.

(1) Laboratory employees and consultants 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 includes, but is not limited to, fraud, embezzlement, perjury, or any other conduct that might cast doubt on the integrity of the anti-doping and medication control program.

(2) Laboratory employees and consultants shall maintain the confidentiality of all of data, items and information received in connection with Doping Control and Medication Control, including, but not limited to, Samples, Testing documentation, and communications with the Agency.

(3) No employee or consultant of any Laboratory may (directly or indirectly) 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.

(4) No employee or consultant of any Laboratory may (directly or indirectly) provide information about a Test Method to a Covered Person (or to any individual or organization acting on his or her behalf) that could be used to avoid the detection of doping. Instead, any such Covered Person (or individual or organization) will be referred to the Agency.

(5) No employee or consultant of any Laboratory may (directly or indirectly) assist a Covered Person in avoiding collection of a Sample (*e.g.,* advice on masking strategies or detection windows). However, this paragraph does not prohibit the publication 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.

(6) If an employee or consultant of a Laboratory is requested to provide evidence in anti-doping proceedings, he or she is expected to provide independent, scientifically valid expert testimony.

(7) Laboratories shall not issue any statements related to their analytical processes or findings, unless otherwise provided in the Protocol or as directed by the Agency or Authority. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be the sole responsibility of the Agency.

(j) Breach and enforceability.

(1) A failure to respect any of the provisions of this Code of Ethics may result in a Laboratory being subject to Disciplinary Proceedings instituted by the Agency to either suspend or revoke its HEAL accreditation or its Agency approval, as applicable.

(2) In addition, a failure to respect any of the provisions of this Code of Ethics may result in staff of a Laboratory being subject to disciplinary action by the Laboratory, resulting in consequences beyond those stipulated under the Laboratory Standards, including potential termination of employment or, where applicable, the imposition of criminal charges.

Rule 6620. Research and Development Activity Requirements

(a) Laboratories must receive a minimum score of 10 points annually:

(1) 5 points for each peer-reviewed manuscript;

(2) 5 points for the production of educational materials;

(3) 5 points for each funded research project;

(4) 5 points for hosting hands-on training workshop for all HEAL Laboratories; and

(5) 2 points for each Laboratory (internal) method development.

(b) The validation or implementation of established anti-doping methods with only minor adjustments, or the repetition of research previously published or presented by others, is not sufficient to be considered as a research and development activity.

7000. Arbitration Procedures

Rule 7010. Applicability

The Arbitration Procedures set forth in this Rule 7000 Series shall apply to all adjudications arising out of the Rule 3000 Series.

Rule 7020. Delegation of Duties

(a) Subject to Rule 3249, Anti-Doping Rule Violations arising out of the Rule 3000 Series and violations of Rule 3229 (together, ''EAD Violations'') shall be adjudicated by an independent arbitral body (the ''Arbitral Body'') in accordance with the Rule 3000 Series and these Arbitration Procedures. The Arbitral Body may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Arbitral Body. The Arbitral Body is selected by mutual agreement of the Authority and the Agency. The Arbitral Body will ordinarily assign a sole arbitrator to hear a case concerning an EAD Violation. However, the Arbitral Body may assign 3 arbitrators to hear a case involving an EAD Violation upon request by the Agency, based on the nature or complexity of the case.

(b) Subject to Rule 3349, Controlled Medication Rule Violations arising out of the Rule 3000 Series, violations of Rule 3329, and violations of Rule 3510 (ECM or Other Violations) shall be adjudicated by an adjudication panel (the Internal Adjudication Panel) in accordance with the Rule 3000 Series and these Arbitration Procedures. The Internal Adjudication Panel may also adjudicate any other matter referred to it under the Protocol, and any other matter that might arise from time to time under the Protocol that the Agency considers should be determined by the Internal Adjudication Panel. The Internal Adjudication panel is selected by mutual agreement of the Authority and the Agency. The Internal Adjudication Panel will ordinarily assign a single Internal Adjudication Panel member to adjudicate a case involving an ECM or Other Violation; in exceptional circumstances only, the Internal Adjudication Panel may assign 3 members to adjudicate a case upon request by the Agency.

(c) Final decisions issued by the Arbitral Body or Internal Adjudication Panel are subject to review as specified in section 3058 of the Act.

Rule 7030. Arbitral Body

(a) The Arbitral Body shall have a pool of arbitrators consisting of a minimum of 5 members appointed by mutual agreement of the Authority and the Agency.

(b) Arbitrators shall be appointed for 4-year terms. Candidate arbitrators shall complete an application in a form designated by the Authority.

(c) Candidates shall not be or have been in the previous 2 years an officer, director, trustee, employee, consultant, or official, or be in a policy making position for any Equine Constituencies or the Agency, except that this requirement does not apply to former State Racing Commission officials or employees.

(d) Candidate arbitrators shall be required to submit on request to a background check before appointment and shall commit in writing to accept appointment to all cases to which they are selected except:

(1) when they have been involved in the Provisional Hearing for the matter;

(2) when they have an actual or perceived conflict of interest; or

(3) for personal hardship (candidates shall agree not to decline appointment for personal hardship in more than 2 cases in any 12-month period, except in exceptional circumstances).

(e) If an arbitrator dies, resigns, becomes incapacitated during the arbitrator's term (legal incapacity is not required), or is removed for an ethical breach or deficiency in carrying out his or her duties, a new arbitrator shall be selected and appointed for a full 4-year term, following the procedures set forth in this Rule 7030.

Rule 7040. Internal Adjudication Panel

(a) The Internal Adjudication Panel shall consist of impartial members appointed by mutual agreement of the Authority and the Agency to hear ECM or Other Violations (''IAP members''). The Internal Adjudication Panel shall have a pool of IAP members. The Authority and the Agency may appoint as many IAP members as they consider necessary to the pool of IAP members in accordance with the Arbitration Procedures.

(b) Candidate IAP members shall be required to submit on request to a background check before appointment and shall commit in writing to accept appointment to all cases to which they are selected except:

(1) when they have been involved in the Provisional Hearing for the matter;

(2) when they have an actual or perceived conflict of interest; or

(3) for personal hardship (candidates shall agree to not decline appointment for personal hardship in more than 2 cases in any 12-month period, except in exceptional circumstances).

(c) IAP members are appointed for 4-year terms.

(d) Apart from appointment to the Internal Adjudication Panel, IAP members shall not have any business or economic interest with a party in a case.

(e) If an IAP member dies, resigns, becomes incapacitated during the IAP member's term (legal incapacity is not required), or commits an ethical breach or deficiency, the Authority or the Agency may remove the IAP member from the Internal Adjudication Panel. The Agency will publish a list of members of the Internal Adjudication Panel on its website.

(f) A person is not precluded from serving as an IAP member concomitantly with his or her service as an association or state steward, provided that doing so does not put that him or her in a position of actual or perceived conflict of interest.

Rule 7050. Training of Arbitrators and IAP Members

Arbitrators and IAP members shall receive at least 2 hours of continuing education each year on issues related to

proper and efficient handling of cases. The education must be approved by the Authority. Failure to complete this required continuing education is grounds for immediate dismissal.

Rule 7060. Initiation by the Agency

(a) EAD Violations. Unless Rule 3249 applies, if the Agency charges a Covered Person with an EAD Violation, the Agency shall initiate proceedings with the Arbitral Body. If a Covered Person is charged with both an EAD Violation and an ECM or Other Violation, the procedures for EAD Violations apply. The parties to the proceeding shall be the Agency and the Covered Person(s) charged. The Owner and the Authority shall be invited to join in the proceedings as observers and, if accepted as such, receive copies of the filings in the case. In the context of EAD Violation cases, the Owner may be permitted to intervene and make written or oral submissions.

(b) ECM and Other Violations. Unless Rule 3349 applies, if the Agency charges a Covered Person with an ECM or Other Violation, the Agency shall initiate proceedings with the Internal Adjudication Panel. The Covered Person may request a hearing before the Internal Adjudication Panel. However, the Internal Adjudication Panel may decide in its sole discretion to determine the matter based solely on the written submissions without a hearing, if the Internal Adjudication Panel considers itself sufficiently well-informed to render a decision on the written submissions alone. The parties to the proceeding shall be the Agency and the Covered Person(s) charged. The Owner and the Authority shall be invited to join in the proceedings as observers and, if accepted as such, receive copies of the filings in the case. In the context of ECM and Other Violation cases, the Owner shall not be permitted to intervene or make written or oral submissions.

(c) Only the following persons may attend hearings as the Owner of the Covered Horse, unless otherwise agreed by the hearing panel:

(1) if the Covered Horse is owned by one individual, that individual;

(2) if the Covered Horse is owned by more than one individual or by a partnership, corporation, limited liability company, syndicate, or other association or entity, the Designated Owner or Managing Owner.

Rule 7070. New or Additional Charges

If after charging a Covered Person with a violation, the Agency has cause to bring any new or different charge(s) against the Covered Person, the charge shall be made in writing and filed with the other party or parties and (as applicable) the Internal Adjudication Panel or Arbitral Body. The arbitrator(s) or IAP member(s) appointed to hear the case shall decide whether the charges should be consolidated and heard in the same proceedings or whether the new or additional charge(s) should be heard separately.

Rule 7080. Expedited Procedures

(a) At the request of any party, any time period set forth in the Arbitration Procedures may be shortened by the arbitrator(s) or IAP member(s) if 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.

(b) Pursuant to Rule 3262 or Rule 3362, the Agency may, in its sole discretion, shorten any deadlines within the Arbitration Procedures proportionately to ensure resolution prior to a Covered Horserace.

(c) If the Agency does not agree to the process being expedited, the arbitrator(s) or IAP member(s), as applicable, shall determine whether the adjudication process shall be expedited and the schedule pursuant to which the process shall proceed.

Rule 7090. Jurisdiction

(a) An arbitrator or IAP member 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.

(b) A party must object to the jurisdiction of the arbitrator(s) or IAP member(s) or to the arbitrability of a charge by the Agency no later than the filing of the answering statement to the charge that gives rise to the objection. The arbitrator(s) or IAP member(s) may rule on such objections as a preliminary matter or as part of the final decision, in his or her sole discretion.

Rule 7100. Consolidation

Matters involving more than one Covered Person may, in the Agency's discretion, be consolidated into a single matter. If an EAD Violation is alleged by the Agency against any of the Covered Persons who are parties in the consolidated matter, the process for EAD Violations will be followed.

Rule 7110. Location and Means of Conducting Hearings

(a) Hearings regarding EAD Violations shall take place in person, unless the arbitrator(s) order(s) the hearing (or parts thereof) to take place by use of an audio-visual teleconferencing system.

(b) Hearings regarding ECM or Other Violations shall take place by use of an audio-visual teleconferencing system, unless the IAP member(s) order(s) the hearing to take place in person.

(c) In-person hearings shall be held in the United States at a location determined by the arbitrator(s) or IAP member(s).

Rule 7120. Qualifications

Any arbitrator(s) or IAP member(s) appointed pursuant to Rule 7130 shall be subject to disqualification for the reasons specified in Rule 7140.

Rule 7130. Appointment of Hearing Panels to Adjudicate Cases

(a) The arbitrator(s) shall be appointed in the following manner: immediately after the initiation of a proceeding by the Agency as set forth in Rule 7060, the Arbitral Body shall appoint a single arbitrator or three (3) arbitrators from the pool of arbitrator(s) on a rotating basis, after confirming that the arbitrator(s) will not decline the appointment due to personal hardship. The arbitrator(s) adjudicating the Provisional Hearing shall not serve as an arbitrator determining the merits of the charge against the Covered Person. The Arbitral Body shall communicate to the parties the name of the arbitrator(s) appointed to hear the matter within 3 days of initiation by the Agency.

(b) The IAP member(s) shall be appointed in the following manner: Immediately after the initiation of a proceeding by the Agency as set forth in Rule 7060, the Internal Adjudication Panel shall appoint a single IAP member (or in exceptional cases three IAP members) from the pool of IAP members on a rotating basis, after confirming that the IAP member(s) will not decline the appointment due to personal hardship. The IAP member(s) adjudicating the Provisional Hearing shall not serve as the IAP member(s) determining the merits of the charge against the Covered Person. The Internal Adjudication Panel shall communicate to the parties the name of the IAP member(s) appointed to hear the matter within 3 days of initiation by the Agency.

(c) Once appointed, the arbitrator(s) and IAP member(s) shall receive an electronic copy of the charge letter, Arbitration Procedures, Rule 3000 Series and related rule series, and the Billing Standards.

Rule 7140. Disclosure and Challenge Procedure

(a) Each arbitrator and IAP member appointed to hear a particular case shall

disclose to the parties any circumstance likely to affect his or her 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.

(b) Upon objection of a party to the continued service of an arbitrator or IAP member, the Arbitral Body or Internal Adjudication Panel (as applicable) shall determine whether the arbitrator or IAP member is evidently partial, and (if so) the arbitrator or IAP member shall be disqualified. The Arbitral Body or Internal Adjudication Panel shall inform the parties of its decision, which shall be final and not subject to review or any other challenge.

Rule 7150. Communication

Once appointed, no party and no Person acting on behalf of any party shall communicate unilaterally concerning the case with any arbitrator or IAP member appointed to hear the case. All communications with the Arbitral Body or Internal Adjudication Panel or any arbitrator or IAP member concerning the case shall include the other party or parties.

Rule 7160. Vacancies

If for any reason following assignment to the case an arbitrator or IAP member becomes unable to perform his or her duties in a particular case, the Arbitral Body or Internal Adjudication Panel (as applicable) may fill the vacancy on a rotating basis as described in these rules.

Rule 7170. Procedures for EAD Violations

(a) For matters involving an alleged EAD Violation arising from an Adverse Analytical Finding, each Covered Person's pre-hearing submission must be filed with the Arbitral Body on or before 14 days after submitting a request for a hearing (or after the deadline to make such request expires), and the Agency's pre-hearing submission must be filed with the Arbitral Body on or before 14 days after the last Covered Person's pre-hearing submission. There shall be no reply pre-hearing submission unless ordered otherwise by the arbitrator(s), but each party may present rebuttal evidence at the hearing.

(b) For matters involving an alleged EAD Violation involving a non-analytical violation or a violation of Rule 3229, the Agency's initial pre-hearing submission must be filed with the Arbitral Body on or before 14 days after the last Covered Person requests a hearing (or after the deadline to make such request expires). Each Covered Person's pre-hearing submission must be filed with the Arbitral Body on or before 14 days after the Agency's initial pre-hearing submission, and the Agency's reply pre-hearing submission must be filed with the Arbitral Body seven 7 days after the last Covered Person's pre-hearing submission.

(c) A Covered Person's pre-hearing submission shall include a brief not to exceed 30 double-spaced single-sided pages and shall include all exhibits, schedules, witness statements, expert reports, and all other evidence (except summaries and demonstrative aides) that 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 the organization (in the case of an organization representative) expected to be called to testify at the hearing, along with signed statements for each of those witnesses. 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.

(d) The Agency's initial pre-hearing submission shall include a brief not to exceed 30 single-sided double-spaced pages for each Covered Person charged in the case and shall include all exhibits, schedules, witness statements, expert reports, and all other evidence (except impeachment evidence, summaries, and demonstrative aides) that 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 the organization (in the case of an organization representative) expected to be called to testify at the hearing, along with signed statements for each of those witnesses. For expert witnesses, the initial pre-hearing submission shall include a C.V. and expert report, identifying all opinions to which the expert will testify, and the facts and scientific methods upon which those opinions are based. The submission shall identify all scientific treatises, studies, or articles on which the expert relies in rendering his or her opinion(s), for each expert included in the witness designations. The Agency's reply pre-hearing submission shall include all additional evidence upon which it intends to rely for rebuttal (except impeachment evidence, summaries, and demonstrative aides) and a reply brief not to exceed 15 single-sided double-spaced pages for each Covered Person charged in the case.

(e) Each party is responsible for updating its disclosures as such information becomes available. If a party should have submitted evidence in the party's pre-hearing submission but did not submit such evidence, the arbitrator(s) shall not admit such evidence absent a showing of good cause.

(f) The hearing should take place no more than 60 days from the date the last Covered Person requested a hearing in a particular case.

(g) At the request of any party, or at the discretion of the arbitrator(s), the arbitrator(s) may schedule, as soon as practicable, a preliminary hearing with the parties or their representatives. The preliminary hearing shall be conducted by telephone or video conference. During the preliminary hearing, the parties and the arbitrator(s) shall discuss any preliminary matters to ensure compliance with the procedures herein.

(h) Upon a showing of exceptional circumstances, the arbitrator(s) may extend any of the deadlines set forth in Rule 7170 for the minimum time necessary to address the circumstance. If all parties agree to an alternative schedule in a particular case, the arbitrator(s) shall alter dates accordingly.

(i) If any of the dates described in Rule 7170 fall on a weekend or a Federal holiday, they shall be moved to the next business day.

Rule 7180. Procedures for ECM and Other Violations

(a) Subject to paragraph (b) below, the IAP member(s) may determine to hold a hearing and require written submissions to be filed prior to the hearing, or to require written submissions and determine the matter based solely on the written submissions without a hearing. The IAP member(s) shall have wide discretion to determine the conduct of the proceedings in order to ensure that they are commensurate to the violations at issue. The IAP member(s) may issue directions to the parties as necessary. The IAP member(s) shall also have discretion to amend any time limits as they see fit in the circumstances, but any extension of deadlines shall be granted only for the minimum time necessary to address the circumstance, as all matters before the IAP member(s) shall proceed expeditiously.

(b) A person charged with a violation may request that the IAP member waive the requirement that written submissions be filed by the parties, and permit the person charged to make an

oral presentation at a hearing. The IAP member may grant the request in the interest of justice, if the conduct of the hearing will not prejudice any of the other parties. The IAP member(s) shall provide the Agency the opportunity to respond to the oral presentation and shall have wide discretion to determine the conduct and scope of the hearing. The person charged may request that he or she be assisted by legal counsel or other representative at the hearing.

(c) If the IAP member(s) order the parties to produce written submissions, and the matter involves an alleged ECM or Other Violation arising from an Adverse Analytical Finding, each Covered Person's submission must be filed with the Internal Adjudication Panel on or before 7 days after submitting a request for a hearing before the Internal Adjudication Panel (or after the deadline to make such request expires), and the Agency's submission must be filed with the Arbitral Body on or before 7 days after the last Covered Person's submission. There shall be no reply submissions unless ordered otherwise by the IAP member(s).

(d) If the IAP member(s) order the parties to produce written submissions, and the matter involves a non-analytical ECM Violation or Other Violation, the Agency's initial submission must be filed with the Internal Adjudication Panel on or before 7 days after the last Covered Person requests a hearing before the Internal Adjudication Panel (or after the deadline to make such request expires). Each Covered Person's submission must be filed with the Arbitral Body on or before 7 days after the Agency's initial submission. There shall be no reply submissions unless ordered otherwise by the IAP member(s).

(e) If the IAP member(s) order the parties to produce written submissions, the submissions of each party shall ordinarily not exceed 15 single-sided double-spaced pages and shall include all supporting documentation on which the party relies. If any party intends to call a witness or expert to testify at the hearing, a signed witness statement and expert report (as applicable) shall be filed with the written submission.

(f) If any of the dates described in Rule 7180 fall on a weekend or a Federal holiday, the date shall be moved to the next business day.

Rule 7190. Exchange of Information

Information shall be exchanged electronically, unless otherwise agreed by the parties. The arbitrator(s) and IAP member(s) are authorized to resolve any disputes concerning the exchange of information between the parties consistent with the expedited nature of the proceedings.

Rule 7200. Participation

The Arbitral Body and Internal Adjudication Panel (and their respective members) shall maintain the confidentiality of the proceedings. The arbitrator(s) or IAP member(s) may proceed without the participation of any party or representative who, after due notice, fails to be present or make a submission. If a party defaults, the arbitrator(s) or IAP member(s) may require the party who is present to submit such evidence and documents as the arbitrator(s) or IAP member(s) may require for the making of a final decision. Hearings are not open to the media or the public. However, the arbitrator(s) or IAP member(s) may permit one or more third parties to attend the hearing.

Rule 7210. Representation

Any party may be represented by legal counsel or other representative. The legal counsel or other representative shall provide a letter of representation notifying the other party and the Arbitral Body or Internal Adjudication Panel (as applicable) of his or her name, phone number, email, and mailing address. A party shall be bound by the statements made and positions taken by its legal counsel or other representative.

Rule 7220. Oaths

All testimony at hearings shall be taken under oath or affirmation.

Rule 7230. Stenographic Record

Any party desiring a stenographic record of all or a portion of the hearing shall notify the other parties of the request at least 7 days in advance of the start of the hearing, unless ordered otherwise by the arbitrator(s) or IAP member(s). The Agency shall identify the court reporter to be used for transcription services, and an electronic copy of the transcript shall be provided to the arbitrator(s) or IAP member(s) (as applicable) and to the parties. Parties are responsible for the costs of any transcript they request.

Rule 7240. Interpreters

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. Interpreters shall have no prior relationship with a party or have any interest in the proceeding, and the arbitrator(s) or IAP member(s) (as applicable) must approve the interpreter in advance. The costs of the interpreter shall be split between the parties. Any document that is not in English shall be officially translated by a certified translator paid for by the party offering or relying upon the document.

Rule 7250. Conduct of Hearings

(a) The Agency shall present evidence to support its charge. The Covered Person(s) charged shall then present evidence to support the Covered Person(s) defense. The Agency is then entitled to present rebuttal evidence. Witnesses for each party shall also submit to questions from the arbitrator(s) or IAP member(s) and the adverse party. The arbitrator(s) or IAP member(s) may vary this procedure, provided that the parties are treated equally and that each party has the right to be heard and is given a fair opportunity to present its case.

(b) The arbitrator(s) or IAP member(s) 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 within the discretion of the arbitrator(s) or IAP member(s) to determine the propriety of the attendance of any other person other than a party and its representatives and the observers identified in Rule 7060.

(c) The arbitrator(s) or IAP member(s) 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.

(d) The parties may agree to waive oral hearings.

Rule 7260. Evidence

(a) The parties may offer such evidence as is relevant and material to the dispute and shall produce such evidence as the arbitrator(s) or IAP member(s) may deem necessary to make a determination in a case.

(b) Prior to or during the hearing, a party may also request the arbitrator(s) or IAP member(s) to order production of any document which the party believes to be relevant and material to the dispute. The arbitrator(s) or IAP member(s) shall have discretion to grant or reject such a request as they see fit in the circumstances. However, requests for discovery and wide-ranging or otherwise disproportionate document requests shall not be permitted.

(c) The arbitrator(s) or IAP member(s) may retain an expert or seek independent evidence only if (i) agreed to by all of the parties and (ii) the parties or the Agency agree(s) 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(s) or IAP member(s) and shall have the right to respond to any independent evidence obtained by the arbitrator(s) or IAP member(s).

(d) The arbitrator(s) or IAP member(s) 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. Evidentiary and other rules for proving violations of the Protocol are also set out in Rule 3120.

(e) The arbitrator(s) or IAP member(s) shall apply relevant principles of legal privilege, including those involving the confidentiality of communications between an attorney and client and the investigative privilege.

(f) The arbitrator(s) or IAP member(s) may issue subpoenas for witnesses, documents, information, or other evidence upon the request of any party, keeping in mind the expedited nature of the proceedings and the procedures set forth in Rules 7170 and 7180. The arbitrator(s) or IAP member(s) shall not issue a subpoena for a deposition, because depositions (along with formal written discovery in civil litigation) are not in keeping with the expedited nature of the Arbitration Procedures.

Rule 7270. Inspection

If the arbitrator(s) or IAP member(s) consider it necessary to make an inspection in connection with a proceeding, the arbitrator(s) or IAP member(s) shall so advise the parties. The arbitrator(s) or IAP member(s) shall set the date and time that shall not delay the procedures in Rules 7170 and 7180 and shall notify the parties. Any party who so desires may be present at such an inspection. If one or all parties are not present at the inspection, the arbitrator(s) or IAP member(s) shall make an oral or written report to the parties and afford them an opportunity to comment.

Rule 7280. Interim Rulings and Measures

The arbitrator(s) or IAP member(s) may make interim rulings and orders, and may order whatever interim measures they deem necessary to provide any party an immediate protection of rights.

Rule 7290. Provisional Hearings

Hearings to resolve challenges to Provisional Suspensions shall be held in accordance with Rule 3247 or 3347, as applicable. Hearsay evidence shall be admissible in a Provisional Hearing.

Rule 7300. Closing of Hearing

Subject to Rule 7310, the arbitrator(s) or IAP member(s) shall declare the hearing closed after the conclusion of closing arguments. Post-hearing briefs shall not be permitted, except as ordered by the arbitrator(s) or IAP members(s) in complex or otherwise exceptional cases. The time limit to issue the final decision shall commence upon the closing of the hearing.

Rule 7310. Reopening of Hearing

To avoid manifest injustice, the hearing may be reopened on the initiative of the arbitrator(s) or IAP member(s), or upon application of a party, at any time before the final decision is made. At the request of a party, the arbitrator(s) or IAP member(s) will determine if the applicable standard has been met to reopen the hearing.

Rule 7320. Waiver of Rules

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.

Rule 7330. Serving of Notice

(a) Any papers, notices, or process necessary or proper for the initiation or continuation of a proceeding under these rules, and any final decision made under these rules may be served by mail or email 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.

(b) Unless otherwise instructed by the Arbitral Body or Internal Adjudication Panel, any documents submitted by any party to the Arbitral Body or Internal Adjudication Panel shall simultaneously be provided to the other party or parties to the proceeding.

Rule 7340. Final Decision

A final decision shall be in writing and signed by the arbitrator(s) or IAP member(s). The arbitrator(s) shall issue the final decision on or before 14 days after the close of the hearing. The IAP member(s) shall issue the final decision on or before 14 days after the last written submission contemplated in Rule 7180 or after the close of the hearing (as applicable). The 14-day time limit may be extended if additional time is needed due to the complexity of the case or exceptional circumstances.

Rule 7350. Scope of Final Decision

Arbitrators and IAP members may grant any remedy or relief authorized by the Act or the Rules issued pursuant to the Act.

Rule 7360. Case Resolution During Proceedings

If the parties settle the case during the course of the proceedings in accordance with Rule 3249 or 3349, the Arbitral Body or the Internal Adjudication Panel shall issue an order terminating the proceedings.

Rule 7370. Notification of Final Decision

(a) The final decision shall be served on all parties by first class mail, email, or personal service. Interested Parties shall also be notified of the final decision.

(b) The final decision shall be Publicly Disclosed and shall not be considered confidential, unless provided otherwise in the applicable rules.

Rule 7380. Modification of Final Decision

Within 7 days of the issuance of a final decision, any party, upon notice to the other parties, may request the Arbitral Body or Internal Adjudication Panel to correct any clerical, typographical, or computational errors in the final decision. The other parties shall ordinarily be given 5 days to respond to the request.

Rule 7390. Release of Documents for Judicial Proceedings

The Arbitral Body and Internal Adjudication Panel (as applicable) 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 Internal Adjudication Panel's possession that may be required in judicial proceedings relating to the proceeding. If the matter is subject to review by an administrative law judge in accordance with the Act, the Arbitral Body and Internal Adjudication Panel (as applicable) shall furnish copies of any documents requested by the administrative law judge to such judge in connection with that proceeding.

Rule 7400. Right of Review

The final decision of the Arbitral Body or Internal Adjudication Panel is subject to review in accordance with section 3058 of the Act. Notwithstanding any provision set forth in these Arbitration Procedures, nothing herein shall alter the standards of review set forth in the Act.

Rule 7410. Applications to Court and Exclusion of Liability

(a) Arbitration is intended to be the exclusive remedy in all cases arising under the Rule 3000 Series, subject to appeal as described in the Rule 3000 Series and the Act.

(b) No civil action commenced by a party relating to the subject matter of the proceeding under the Arbitration Procedures shall be deemed a waiver of any party's right to adjudicate that party's case under the Arbitration Procedures.

(c) Neither the Arbitral Body nor the Internal Adjudication Panel (nor any arbitrator or IAP member) in a proceeding under these rules is a necessary party in judicial proceedings relating to that proceeding.

(d) Parties to a proceeding under the Arbitration Procedures shall be deemed to have consented that a final decision may be entered in any Federal or State court having jurisdiction, unless the party seeks review pursuant to section 3058 of the Act.

(e) None of the Authority, Agency, Arbitral Body, Internal Adjudication Panel, arbitrators, or IAP members shall be liable to any party for any act or omission in connection with any proceedings conducted under these Arbitration Procedures.

Rule 7420. Costs

(a) 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.

(b) 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.

(c) 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 charges or defenses to charges (as applicable) and result in imposition and publication of sanctions requested by the Agency.

(d) The Authority shall be solely responsible for the administrative costs stemming from IAP member-resolved cases as described in the Arbitration Procedures.

Rule 7430. Expenses

The expenses of witnesses for any party shall be paid by the party producing such witnesses. Each party shall bear its own attorneys' fees and other expenses.

Rule 7440. Arbitrator's Compensation

(a) Arbitrators shall be compensated and reimbursed in a manner consistent with the Billing Standards.

(b) If there is disagreement concerning the terms of compensation, the disagreement shall be resolved as described in the Billing Standards.

(c) 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.

(d) Arbitrator fees and IAP member fees shall be paid in accordance with Rule 7420.

Rule 7450. Application of Rules

The Rule 1000–9000 Series shall be considered part of the agreement to arbitrate and in all instances the arbitrators and IAP members are required to apply the provisions of that arbitration agreement and conform to its terms.

By direction of the Commission.

Joel Christie,

Acting Secretary.

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