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~~Unless specified otherwise, 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. A Technical ~~Letters~~Letter 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 applicant 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~~are 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~~their 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~~ Rule 6260(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~~ Rule 6130(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~~suitable professional liability ~~risk~~ insurance coverage ~~has been obtained to cover liability of no less than $5,000,000 annually~~, as approved by the Agency and the Authority.

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~~ Rule 6260(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~~ Rule 6120(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~~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 the program effective date, 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~~may be conducted ~~by the Laboratory alone or~~ in cooperation with other Laboratories, other laboratories approved by the Agency, 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~~on request to demonstrate that they continue to maintain suitable 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)~~, as approved by the Agency and the Authority.

(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 and Medication 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~~ISO/IEC 17025 accredited 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~~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); and

(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~~chain of ~~Custody~~custody up to Sample reception by the subcontracted ~~Laboratory~~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~~If deemed necessary by the Laboratory ~~shall~~or requested by the Agency, the Laboratory will measure and report 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~~, and perform other tests that may assist in the evaluation of possible adulteration or manipulation ~~may be performed, if deemed necessary by the Laboratory~~of Samples.

(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~~(and related Metabolites and Markers) or use of 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~~Racetrack Safety Program or other regulations; ~~or~~and

(5) Additional analyses for quality assurance/quality improvement/method development or research purposes, in accordance with the requirements indicated in ~~Rule~~Rules 6320 and 6600.

(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~~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~~3 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.

(6) The Laboratory shall create a video recording of the opening and identification of the B Sample and provide a copy of that video to the Agency.

(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 2 B 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) 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. Ensuring 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~~Person's and 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.

(3) If the Laboratory detects nandrolone and testosterone in a Sample reported to be derived from a gelding during the Initial Testing Procedure, the Laboratory should immediately report that finding to the Agency before proceeding with the Confirmation Procedure. The Agency will then promptly investigate whether cryptorchidism could explain the reported finding. If the Agency is satisfied that the Covered Horse suffers from cryptorchidism, and that such condition explains the reported finding, the Agency will instruct the Laboratory not to continue with the Sample analysis procedures. If the Agency is not satisfied that the Covered Horse suffers from cryptorchidism, or that such condition cannot explain the reported finding, the Agency will instruct the Laboratory to complete the Sample analysis procedures.

(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~~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~~chain of ~~Custody~~custody. The Laboratory shall keep all ~~Chain~~chain of ~~Custody~~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 as determined by the Agency. 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~~chain of ~~Custody~~custody. The Laboratory shall keep all ~~Chain~~chain of ~~Custody~~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.

(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 as determined by the Agency.

(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 as determined by the Agency.

(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~~chain of ~~Custody~~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~~chain of ~~Custody~~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~~chain of ~~Custody~~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. Unless directed otherwise by the Agency, the Laboratory shall retain copies of each video recording of the identification and opening of a B Sample for the duration of Sample storage or until final resolution of a case where all rights of appeal or review have been exhausted or waived, whichever is later.

(vii) If Sample(s) are transported to another Laboratory for long-term storage, the Sample's external ~~Chain~~chain of ~~Custody~~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~~custodian:

(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~~chain of ~~Custody~~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. The Laboratory shall transfer the Sample's external ~~Chain~~chain of ~~Custody~~custody and other non-analytical records to the Agency, either as originals or copies, immediately or upon request.

(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~~Research in support of Doping Control, Medication Control, or horse welfare. 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, other laboratory approved by the Agency, or a third-party research institution or group, or wishes to partner with another Laboratory, other laboratory approved by the Agency, 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.

(5) The Agency may also direct the Laboratory to transfer custody of any Sample to another Laboratory or other laboratory approved by the Agency, or direct that an additional Sample (e.g., an additional blood tube or lock of hair) be sent directly to another Laboratory or other laboratory approved by the Agency, in each case for purposes of additional analysis and research relating to horse welfare (e.g., fatality or injury analysis and research).

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 [$z = (y - \hat{y})/\delta$], where 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~~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~~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~~6130(c);

(3) Failure to analyze the minimum number of Samples indicated in ~~paragraph (i) of~~ Rule 6130(h) (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 Internal 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~~Finding(s) 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, Medication Control, and horse welfare.

(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 and Medication 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. and Medication Control. Laboratories may also carry out research for purposes of improving horse welfare (*e.g.*, research to understand and reduce equine fatalities and injuries).

(3) Laboratories are expected to conduct research on Equineequine (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 hertheir 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 Controlan adjudication under the Protocol and the Arbitration Procedures, 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~~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~~the Covered Person's behalf~~)~~ that could be used to avoid the detection of doping or misuse of Controlled Medication Substances or Methods, or other wrongdoing. 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.

Summary report: Litera Compare for Word 11.4.0.111 Document comparison done on 10/11/2023 19:06:19	
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Modified filename: 6000. Laboratory Standards - Nov 10, 2023.docx	
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Move To	1
Table Insert	0
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