RULE SERIES 6000

EQUINE STANDARDS FOR LABORATORIES AND ACCREDITATION

6000. EQUINE STANDARDS FOR LABORATORIES AND ACCREDITATION.

Rule 6010. Equine Standards for Laboratories.

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

(c) Compliance with the ESL in effect at the time of Sample analysis (as opposed to another alternative standard, practice, or procedure) shall be sufficient to conclude that the procedures covered by the ESL were performed properly. A failure by a Laboratory to follow a requirement in effect at the time of Analytical Testing, which has subsequently been eliminated from this ESL or applicable Technical Document(s) or Technical Letter(s) at the time of a hearing, shall not serve as a defense to an anti-doping rule violation.

Rule 6020. Technical Documents.

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

(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 extreme circumstances a Suspension of the Laboratory's HEAL accreditation, may be warranted as determined by the Agency.

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(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.

[1] The Agency will provide guidance to Laboratories, and other Agency stakeholders on the standard(s) that may be affected by a new Technical Document in the Summary of Modifications that accompanies the publication of the revised version of the 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.[2]

(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, as 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.[3]

Rule 6030. Technical Letters.

(a) Technical Letters are issued in letter format on an ad-hoc basis to provide direction to the Laboratories on particular issues on the analysis, interpretation and reporting of results for specific Prohibited Substance(s) or Prohibited Method(s) or on the application of specific Laboratory procedures. Technical Letters are modified or withdrawn by the Agency as appropriate.[4]

[2] For example, if the application of a newly approved Technical Document results in an Adverse Analytical Finding for a Sample with a collection date prior to the effective date of that new Technical Document, which would not have resulted in an Adverse Analytical Finding with the application of the currently effective version of the Technical Document in effect at the time of Sample collection, the Laboratory shall report the finding as a Negative Finding. In addition, the Laboratory shall record the details of the finding as a comment in the Negative Finding Test Report.

[3] For example, if the application of a newly approved *Technical Document* results in an *Adverse Analytical Finding* for a *Sample* with a collection date prior to the effective date of that new *Technical Document*, which would not have resulted in an *Adverse Analytical Finding* with the application of the currently effective version of the *Technical Document* in effect at the time of *Sample* collection, the *Laboratory* shall report the finding as a *Negative Finding*. In addition, the *Laboratory* shall record the details of the finding as a comment in the *Negative Finding* Test Report.

[4] Archived versions, including effective dates, will be available on the *Agency's* website as applicable.

(b) Technical Letters are drafted and approved by the Agency and Authority, in consultation with relevant scientific experts, and published on the Agency's website. Technical Letters become effective immediately, unless otherwise specified by the Agency.[5]

(c) Once approved, a Technical Letter becomes an integral part of the ESL and supersedes any previous publication on a similar topic,[6] including Technical Document(s) or the ESL.

(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.

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Rule 6040. Laboratory Guidelines.

(a) Laboratory Guidelines are issued to provide direction to the Laboratories on new Analytical Methods or procedures approved by the Agency. Laboratory Guidelines are modified or deleted by the Agency, as appropriate.

(b) Laboratory Guidelines are approved by the Laboratory Expert Group (LabEG).

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(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 are issued to Laboratories to provide detailed technical guidance on the performance of specific Analytical Methods or procedures.

(b) Technical Notes are 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.

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[5] *Technical* Letters may require actions [(e.g., validation of new *Analytes* or modifications to *Analytical Testing Procedures*, the procurement of *Reference Material(s)* or *Reference Collection(s)*], which may justify that its application cannot be immediate. In such cases, the *Agency* shall make a time provision for implementation and specify an effective date for the *Technical Letter*.

[6] The *Agency* will provide guidance to *Laboratories*, and other *Agency* stakeholders on the standard(s) that may be affected by a new *Technical Letter* in the Summary of Modifications that accompanies the publication of the revised version of the *Technical Letter*.

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

Rule 6070. Racing Medication and Testing Consortium Accredited Laboratories.

(a) This ESL 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 which has already been provided as part of their RMTC accreditation, and which the laboratory checks to confirm it is still current and valid, may with the agreement of the parties be provided to the Agency.

6100. LABORATORY ACCREDITATION AND OPERATING STANDARDS.

Rule 6110. Process and Requirements for HEAL Laboratory Accreditation.

(a) *Applicant Laboratory for HEAL accreditation*. Only a laboratory that satisfies the criteria in this Rule 6110 may apply to become a candidate laboratory for HEAL accreditation.

(1) The applicant laboratory shall submit a completed Application Form, provided by the Agency, duly signed by the Laboratory Director (or equivalent position) and, if relevant, by the Director (or equivalent position) of the host organization (e.g., university, 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 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 the Agency candidate laboratory status and thereby continue within the HEAL accreditation process. Additional supporting documentation may be requested by, and at the discretion of the Agency.

(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

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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), 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;[7]

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

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

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

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[7] If this is covered by other accreditation such as ISO/IEC 17025, the laboratory may refer to this.

(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 in Rule 6610. Candidate laboratories shall not accept samples directly from individual Covered Persons or from individuals or organizations acting on their behalf.

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(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 ten (10) blind EQAS samples arranged by the Agency.[8] The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in the Rule 6200 and 6400 Series, respectively.

(iii) The candidate laboratory shall report the results for the PPT blind EQAS samples to, and in a form designated by, the Agency (in compliance with paragraph (e) of Rule 6260) within thirty (30) days, unless otherwise requested by the laboratory and agreed to by the Agency.

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(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 ten (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 thirty (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 nonconformity(-ies), to allow the candidate laboratory to implement the necessary improvements. Corrective actions, if requested,

[8] Blind *EQAS* samples are generally not sent consecutively.

shall be conducted, and reported by the candidate laboratory to the Agency within thirty (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) Obtaining ISO/IEC 17025 Accreditation by the Laboratory.

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

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

(iii) The Accreditation Body shall send a summary of the Assessment Report and any corrective/preventive action documentation addressing nonconformities, to the Agency. In the event that the candidate laboratory prefers to send the information directly to the Agency, the laboratory shall do so within a reasonable timeline.

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

(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 (d) of Rule 6130.

(8) *Professional Liability Insurance Coverage*. Before the Agency grants accreditation, probationary laboratories shall provide documentation to the Agency demonstrating that they have adequate provisions for self-insuring, or professional liability risk insurance coverage has been obtained to cover liability of no less than one (1) million USD annually.

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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 two (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 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[9] 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 fifteen (15) blind EQAS samples selected from the routine EQAS program.[10] 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.

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

(4) The probationary laboratory shall successfully report the results for the blind EQAS samples in the FAT to the Agency in accordance with paragraph (e) of Rule 6260 within thirty (30) days of opening the samples, unless 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 ten (10) days of the Agency request or as otherwise indicated by the Agency;

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[9]Such as reasonable travel and accommodation expenses and time for accessors.
[10] Blind *EQAS* samples are generally not sent consecutively.

(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 thirty (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 thirty (30) days, or as otherwise indicated by the Agency. The nonconformities identified in the FAT EQAS and the Assessment Report shall be satisfactorily addressed by the laboratory and the recommendations for improvement shall be implemented before accreditation can 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 that 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 six (6) additional months to correct and improve any pending nonconformity(-ies). 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 conducted at the probationary laboratory's expense. A probationary laboratory that fails to provide satisfactory improvements, as determined by the Agency after six (6) months may be required to renew its candidacy as described in Rule 6110 or to restart the probationary phase of accreditation in accordance with paragraph (a) of this Rule 6120.

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

Rule 6130. Maintaining HEAL Accreditation.

(a) *Maintain ISO/IEC 17025 Accreditation*.

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

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

(b) *Flexible Scope of ISO/IEC 17025 Accreditation*[11].

(1) A Laboratory may modify or add Analytes to Analytical Testing Procedures, which are included within its Scope of ISO/IEC 17025 Accreditation or develop new Analytical Testing Procedure(s) that involve technology already included within the Scope of ISO/IEC 17025 Accreditation, without the need for approval by the Accreditation Body that provides the ISO/IEC 17025 accreditation of that Laboratory.[12]

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

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

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

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[11]See ILAC-G29/06:2020 "Guidelines for harmonization of scopes of ISO/IEC 17025 accreditation of the *Agency* anti- doping laboratories".

[12] The flexible system of ISO/IEC 17025 *Laboratory* accreditation shall be based on the overall assessment by the Accreditation Body of the demonstrated competence of the *Laboratory* in the implementation of Laboratory processes and procedures when following a *Flexible Scope of ISO/IEC 17025 Accreditation* system. The flexible system of ISO/IEC 17025 Laboratory accreditation is important to ensure that Laboratories can adapt their Analytical Testing Procedures to the detection of new *Prohibited Substances* or *Prohibited Methods*, as well as to the application of new technical and scientific developments in *Analytical Testing* for *Doping Control*.

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

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

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

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

(c) *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.

(d) *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.[13]

(2) In order to be administratively independent, the Laboratory cannot be administered by, connected or subject to a State Racing Commission, sport organization or other government body responsible for sport performance, including their Board Members, staff, State Racing Commission members or officials. This is necessary to avoid potential conflicts of interest

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[13] *Laboratories* shall comply with these requirements of administrative and operational independence by 1 July 2022, unless otherwise approved by the Agency.

and ensure full confidence in the Laboratory's competence, impartiality, judgment and operational integrity, in compliance with ISO/IEC 17025.

(3) In order to be operationally independent, the Laboratory shall manage its own affairs without hindrance, interference or direction from any Person.[14] 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.

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

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

(e) *Document Compliance with the Agency Laboratory Code of Ethics*.

(1) The Laboratory shall comply with the provision(s) 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 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 report to the Agency. However, if Laboratory staff suspect that the Laboratory Director may have breached the Code of Ethics, the Laboratory staff shall report the alleged breaches of the Code of Ethics directly to the Agency. The Laboratory Director 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.

(f) *Document Implemented Research and Development Activities*.

[14] Except in accordance with the ESL

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

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

(3) The annual research summary will be evaluated and scored by the LabEG. The Laboratory must, except where otherwise agreed by the Agency, achieve the minimum requirement to meet accreditation research requirements in Rule 6620.

(g) *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 (1) annual contribution to an anti-doping symposium or conference. Laboratories are encouraged to participate in collaborative research projects with other Laboratories, and to exchange experience, protocols, arrange for visits of specialists and provide training to other Laboratories and probationary laboratories in specific areas of Analytical Testing.

(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.

(h) *Maintain Professional Liability Insurance Coverage*. Laboratories shall provide documentation to the Agency including evidence that professional liability risk insurance coverage is maintained of no less than two (2) million USD annually (for example, evidence of timely payment of applicable fees and premiums).

(i) *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.[15] The Agency will monitor the number of samples tested by the Laboratory. If the number of samples falls below the minimum, the Laboratory's HISA accreditation may be suspended in accordance with 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.

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[15] To determine the minimum number of *samples*, each urine *sample*, blood *sample* (excluding samples submitted for TCO_2 analysis only) analyzed by the *Laboratory*, regardless of if collected as a 'paired' sample, shall count as an individual *sample*.

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(j) *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).

(k) *Participating in the Agency / Accreditation Body Re-assessments and Continuous Assessments during the Accreditation Cycle*.

(1) Accreditation Body Re-assessment or Continuous Assessment during the Accreditation.

(2) The assessment team shall include at least one ESL-trained assessor selected by the Accreditation Body for the assessment/re-assessment.

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

(4) 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.

(5) *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.[16]

(6) 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 a Laboratory(-ies) chosen 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 ESL and related Technical Documents and Technical Letters. In addition, the Agency shall also conduct an annual review of EQAS results and of relevant routine Analytical Testing issues to assess the overall performance of each Laboratory and to decide its accreditation status.

(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

[16] *Agency* assessments are likely to be not more than five (5) years apart

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., ESL, Technical Documents and Technical Letters), as well as other, non-analytical performance criteria. At the same time, the EQAS also represents, via its educational components, a source of continuous improvement for the effectiveness of the Analytical Testing Procedures.

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[17] will consist of:

(1) At least fifteen (15) blind EQAS samples, distributed by the Agency in multiple rounds;

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

(3) At least three (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;

(4) As part of the Agency 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*. 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).

(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, 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).*

[17] In order to prevent duplication of efforts and extra expense, the *Agency* should collaborate with existing EQAS programs to such as those implemented by RMTC and/or AORC where programs are fit-for-purpose and samples meet EQAS program requirements.

(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 might 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.

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(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, etc.), 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).

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(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 MPRL and the MRPL (applicable only to Non-Threshold Substances prohibited at all times and with no Minimum Reporting Levels); Non-Threshold Substances with Minimum Reporting Levels or other limits controlling them (e.g., substances prohibited on Race Day only), will normally be present in estimated concentrations greater than (>) 120% of the applicable Minimum Reporting Level; Concentrations of the Prohibited Substance and/or its Metabolite(s) or Marker(s) below (<) 50% of the applicable MRPL (for Non-Threshold Substances prohibited at all times with no Minimum Reporting Levels, for educational purposes).

(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 the relevant Technical Document(s) or Laboratory Guidelines; At less than (<) 50% of the Threshold for those Threshold Substances specified in the TD DL whose presence shall be reported if detected in the presence of diuretics or masking agents.

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 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

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Testing Procedures described in the Laboratory's SOPs 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 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 6329) 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).

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

(f) *Reporting Double-Blind EQAS Results*.

(1) The Laboratory shall report the results of double-blind EQAS samples as per Rule 6329.

(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 for valid reasons

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

(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 nor 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) and/or Metabolite(s) and/or Marker(s), or of the identified Marker(s) of Prohibited Method(s), as estimated during method validation of the Initial Testing Procedure.

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

(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 has done for routine samples, in accordance with the relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines.

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6300. ANALYSIS OF SAMPLES.

Rule 6301. Application of ISO/IEC 17025 to the Analysis of Samples.

(a) *Introduction and Scope.* This section of the ESL is intended as an extension of the application of ISO/IEC 17025 and ILAC-G7 to the field of Doping Control. Any aspect of Analytical Testing or management not specifically discussed in this document or in the relevant Technical Documents, Technical Letters or Laboratory Guidelines shall be governed by ISO/IEC 17025. The application focuses on the specific parts of the processes that are critical with regard to the quality of the laboratory's performance as a Laboratory and are therefore significant in the evaluation and accreditation process.

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

(1) Structural and Resource Requirements;
(2) Process Requirements; and
(3) Management Requirements.

Rule 6302. Structural and Resource Requirements.

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

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

Rule 6303. Laboratory Personnel.

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

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

(c) The Laboratory shall have access to records for every Person employed by, or under contract with, the Laboratory including a curriculum vitae or qualification form(s)/certificate(s), a job description, records of completed and ongoing training and records of authorization to perform their defined duties.

Commented [SS3]: This is required by ISO-17025.

(d) Specific criteria shall be met by the Laboratory Director, Laboratory Quality Manager, Laboratory Certifying Scientists, and Laboratory Supervisory Personnel, as outlined in paragraphs (e) through (h) of this Rule 6303.[18]

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

Commented [MSW4]: Should be professional member of AORC. Check with Scott what other laboratory personnel should be required to be AORC members.

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

(f) *Laboratory Quality Manager*. The Laboratory shall have a single staff member appointed as the Laboratory Quality Manager. The Quality Manager shall have responsibility and authority to implement and ensure compliance with the Management System. The Quality Manager's priority and functions shall be focused on quality assurance and quality control activities. The Quality Manager shall remain independent, as much as possible, from routine

[18] *The actual job titles may differ, but qualified personnel will have the overall responsibilities as defined below.*

Laboratory analytical activities. By January 1, 2025 the Quality Manger shall be independent from routine Laboratory analytical activities. Quality control activities including ISO/IEC 17025.

(g) *Laboratory Certifying Scientists*. The Laboratory shall have qualified personnel to serve as Certifying Scientists to review all pertinent analytical data, Analytical Method validation results, quality control results, Laboratory Documentation Packages, and to attest to the validity of the Laboratory's test results. These Certifying Scientists should be members of the Association of Racing Chemists ("AORC").

(h) *Laboratory Supervisory Personnel*. The Laboratory shall have qualified personnel to serve as Laboratory Supervisors. All Laboratory Supervisors shall have a thorough understanding of the Laboratory's Management System including the review, interpretation and reporting of test results, the maintenance of Laboratory Internal Chain of Custody, and proper implementation of corrective and preventive actions in response to analytical problems. These Supervisory Personnel should be members of the AORC.

Rule 6304. Laboratory Facilities.

(a) The Laboratory shall have Fit-for-Purpose facilities including sufficient space for dedicated administrative, sample handling, sample storage and analytical areas, which comply with the following security requirements:

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

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

(3) Two (2) main levels of access shall be defined in the Management System and evaluated in the threat assessment plan:

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

(ii) Controlled Zones: Access to these areas shall be monitored (e.g., through the use of electronic access system(s) such as biometric or personal identification cards) and records of access by visitors shall be maintained;

(4) Access to the Laboratory Controlled Zones shall be monitored and restricted to Laboratory staff and temporarily approved/authorized personnel (e.g., maintenance engineers, auditing teams). All other visitors to the Laboratory Controlled Zones shall be continuously escorted by Laboratory staff member(s). Access to the Laboratory Controlled Zones shall be defined in the Laboratory's Management System.

(5) The Laboratory shall have a dedicated and restricted area within the Controlled Zone for sample receipt and aliquot preparation;

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(6) Access to the Laboratory's sample receipt and aliquot preparation area shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.

(7) The Laboratory shall have a dedicated and restricted sample storage area;

(8) Access to stored samples[19] shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.

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

Rule 6305. Relocation of Laboratory Facilities.

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

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

(b) Relocation date(s) including date of closing of existing facility operations and date of opening of future facility operations;

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

(d) New Laboratory contact information and coordinates.

Rule 6306. Environmental Control.

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

(b) The Laboratory's storage and handling of controlled substances shall comply with applicable national legislation.

(c) The Laboratory shall:

[19] This 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*.

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(1) Ensure appropriate safeguards to electrical service (for example, by provision of an alternative power supply such as a UPS system or power generators, due to costs and complexity, this could be laboratory-wide or instrument-specific) and environmental conditions (space, temperature, humidity, as applicable) for all Laboratory instrumentation and equipment critical to Laboratory operations, such that service is reasonably maintained and any damage is minimized should there be a power interruption.

(2) Have policies in place to ensure the integrity of refrigerated or frozen stored samples in the event of an electrical or freezer/refrigerator equipment failure.

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Rule 6307. Confidentiality of Data, Information and Operations.

(a) The Laboratory shall either file securely any confidential or sensitive information or properly destroy it before disposal. Laboratory staff shall be appropriately trained to comply with confidentially requirements.

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

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Rule 6308. Control and Security of Electronic Data and Information.

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

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

(c) The Laboratory shall implement a data and information management system, a software-based solution that supports and maintains proper traceability of Laboratory operations (e.g., a Laboratory Information Management System, LIMS) with secure and restricted access to stored electronic data by authorized personnel as well as information and data exchange capabilities including between the Laboratory and the Agency.[20]

(d) The Laboratory shall utilize a secure data storage system that prevents unauthorized access and data loss (e.g., failed hard drive, fire, flooding). The Laboratory shall ensure that at least two (2) independent, regularly backed-up copies of all relevant analytical/LIMS/instrument software files are available. If the Laboratory is utilizing a non-cloud-based system, then at least one (1) backup copy shall be stored in a restricted and secure environment either in the Laboratory (e.g., fire and waterproof safe) or in a secure off-site location (e.g., in a mirrored server that guarantees the integrity of the server and the stored data); If the Laboratory is using a cloud-based

[20] The data and information management system may also feature workflow management, data tracking support, *Sample* and *Aliquot Laboratory Internal Chain of Custody*, control of stocks of *Reference Materials*, etc.

system, the Laboratory data shall be, at a minimum, replicated in two different physical locations (e.g., between two different availability zones within the same region or between different regions) in order to minimize the possibility of data loss.

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

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

Rule 6309. Laboratory Equipment.

Commented [SS5]: This section is already covered by ISO-17025.

(a) The Laboratory shall have access to equipment that is required for the correct performance of Analytical Testing activities. The Laboratory shall maintain sufficient instrumental capacity to minimize the risk of operational delays and meet the analytical and results reporting obligations. A list of available equipment shall be established and maintained. All maintenance, service, and repair of equipment shall be recorded.

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

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

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

Rule 6310. Metrological Traceability.

(a) *Reference Materials*. When available, Reference Materials of substances traceable to a national standard or certified by a body of recognized status (e.g., USP, BP, Ph.Eur. WHO) or a Reference Material producer accredited to ISO 17034 shall be used. When a Reference Material is not certified, the Laboratory shall verify its identity and check its purity by comparison with published data or by chemical characterization.

(b) *Reference Collections*. Samples or isolates may be obtained from in vitro or in vivo sources [e.g., (i) an external quality control sample, (ii) an isolate from a urine or blood sample after an authenticated administration, or (iii) an "in-vitro" incubation with liver cells, microsomes or biological fluids] and be used as Reference Collections. Reference Collections shall be traceable to a Prohibited Substance or a Prohibited Method, and the analytical data shall be sufficient to establish the identity of the Analyte.

Rule 6311. Subcontracting of Analysis.

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

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

(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 justifications such as a need for higher sensitivity or specific equipment or expertise, temporary workload or technical incapacity;

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

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

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

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Rule 6312. Purchasing of Services and Supplies.

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

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

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

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

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

Rule 6313. Process Requirements.

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

(b) *Reviewing of Requests, Tenders and Contracts.* Review of legal documents or agreements related to Analytical Testing shall meet the requirements of ISO/IEC 17025.

Rule 6314. Reception, Registration and Handling of Samples.

(a) The Laboratory may receive samples, which have been collected, sealed and transported to the Laboratory according to the Equine Testing and Investigations Standards.

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

(c) The sample transport container and each individual sample shall be inspected, and any irregularities recorded (see Rule 6316). However, samples transferred for long-term storage purposes are not subject to an individual inspection by the receiving Laboratory until a sample has been selected for Further Analysis.

(d) The Laboratory shall have a system to uniquely identify the samples and associate each sample with the collection document or other external chain of custody information.

Rule 6315. Acceptance of Samples for Analysis.

(a) The Laboratory shall analyze each sample received, unless, unless otherwise instructed by the Agency.

(b) If justified by the sample irregularities observed (see Rule 6316), the Laboratory shall seek instructions from the Agency on the performance of Analytical Testing on the Sample. The Agency shall inform the Laboratory in writing whether a Sample with noted irregularities shall be analyzed or not, or of any further measures to be taken (e.g., splitting the Sample in accordance with Rule 6317, forensic analysis, DNA analysis), or that the Sample shall be stored for Further Analysis. The communication between the Laboratory and the Agency shall be recorded as part of the Sample's documentation.

Rule 6316. 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:

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(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 requested Analytical Testing menu, is not provided, e.g., missing or incomplete sample collection documentation;

(3) Sample identification is questionable. For example, 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 requested Analytical Testing menu;

(9) The sample contains foreign objects, such as insects;

(10) The sample condition(s) is unusual – for example: color, odor, presence of turbidity or foam in a urine sample; color, hemolysis, freezing or clotting of a blood sample; unusual differences in sample appearance (e.g., color or turbidity) between the "A" and the "B" Samples.[21]

(c) When an analysis on a sample with documented irregularities is performed, the Laboratory shall record the irregularities in the Test Report.

Rule 6317. 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 shall inform the Laboratory of its decision in writing within three (3) days of notification by the Laboratory. If the Agency decides not to proceed with the sample splitting procedure, then the Laboratory shall report the sample as Not Analyzed to, and in a form designated by, the Agency, including the noted sample irregularities and the documented reasons if provided by the Agency.

(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

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[21] Further guidance on assessing the differences between "A" and "B" *Samples* is provided in a *Technical Letter*.

as the "B" sample, shall be resealed and stored frozen for "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 6325 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 practical after Laboratory reception to obtain the serum or plasma fraction. The centrifuged sample shall be stored frozen in the sealed sample collection tube according to established protocols until the sample opening/splitting procedure can be conducted. The opening of the sample for the splitting of the serum/plasma fraction and resealing of the second fraction shall be carried out as described immediately above.

Rule 6318. 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 tip) 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 (all Initial Testing Procedures or all intended Confirmation Procedures, as applicable), by decanting the Aliquot from the urine sample container into a secondary container (e.g., a Falcon tube). Procedure-specific Aliquot(s) shall then be taken from the secondary container.

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

(3) Urine "A" samples shall be frozen after Aliquots are taken for the Initial Testing Procedure(s) to minimize risks of sample microbial degradation. Urine "B" samples shall be stored frozen after reception until analysis, if applicable.

(c) *Blood Samples*. The Laboratory shall follow the applicable Technical Document(s) and Technical Letter(s) for handling and storing blood samples.

Rule 6319. 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

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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).

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(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.

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

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

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(B) Limit of Identification (LOI): When the analyses of Non-Threshold Substances are based on chromatographic-mass spectrometric techniques, the Laboratory shall determine the lowest concentration at which each Non-Threshold Substance or its representative Metabolite(s) or Marker(s), for which a Reference Material is available, is identified

at no more than 5% false negative rate (in compliance with the applicable Technical Document, Technical Letter or Laboratory Guidelines). The LOI shall be lower than the applicable MRPL;

(C) 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;

(D) Carryover: The conditions required to eliminate carryover of the substance of interest from sample to sample during processing or instrumental analysis.[22]

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(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 the applicable Technical Document and shall follow applicable 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 relevant 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.

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(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.

[22] 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.

(5) Validation of Confirmation Procedures for Threshold Substances.

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

(A) Selectivity, LOI, Robustness, Carryover;

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

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

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

(E) 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;

(F) 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;

(G) Measurement Uncertainty (MU): The MU associated with the results obtained with the quantitative Confirmation Procedure shall be estimated in accordance with the applicable Technical Document, Technical Letter or Laboratory Guidelines. At least, MU at levels close to the Threshold shall be addressed during the validation of the quantitative Confirmation Procedure.

(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 6320. Sample Analysis.

(a) Laboratories shall analyze samples collected by the Agency using Race Day or Out-of-Competition Analytical Testing menus to detect the presence of Prohibited Substances or Prohibited Methods only (as defined in the Prohibited List).

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(b) Covered Persons and their representatives are not permitted to be present for any aspect of sample analysis or processing described in the ESL, Technical Documents, Technical Letters,

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Laboratory Guidelines, or Laboratory SOPs. In addition, Covered Persons are not permitted to have a sample transferred to be tested at a laboratory.

(c) Laboratories may analyze samples for the following, in which case the results of the analysis shall not be reported as an Atypical Finding or an Adverse Analytical Finding:

(1) Non-prohibited substances or methods that are included in the Agency Monitoring Program;

(2) Non-prohibited substances for results interpretation purposes (e.g., non-prohibited substances that share Metabolite(s) or degradation products with Prohibited Substances), if applicable;

(3) Non-prohibited substances or methods requested as part of a Results Management process by an adjudicatory body or the Agency;

(4) Non-prohibited substances or methods requested by the Agency as part of its safety Protocol, Protocol of conduct or other regulations (see comments to Protocol); or

(5) Additional analyses for quality assurance/quality improvement/method development or research purposes, in accordance with the requirements indicated Rule 6333.

(d) At minimum, all Laboratories are required to implement all mandatory Analytical Testing Procedures, as determined by the Agency in compliance with relevant Technical Document(s) and Technical Letter(s).[23] 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 ESL and the applicable Technical Document(s), Technical Letter(s) or Laboratory Guidelines prior to its application to the analysis of samples. In such cases, the Laboratory may be required to provide method validation documentation or EQAS performance data in support of an Adverse Analytical Finding.

(g) Laboratories may, on their own initiative and prior to reporting a test result, apply additional Analytical Testing Procedures to analyze samples for Prohibited Substances or Prohibited Methods not included in the standard Analytical Testing menu, provided that the additional work is conducted at the Laboratory's expense and does not significantly affect the

[23] *Analytical Method* included in the Scope of ISO/IEC 17025 Accreditation. However, based on *Race Day* or *Out-of-Competition Analytical Testing* menu, a mandatory *Analytical Testing Procedure* is not necessarily applied to all *samples*. For some *samples*, the *Agency* may decide to request *Analytical Testing* for specific *Prohibited Substances* or *Prohibited Methods* only. On occasion, however, certain *Analytical Testing Procedures* (e.g., gene doping) or the analysis of certain *Prohibited Substances* (e.g., some large peptides) or *Prohibited Methods* (e.g., gene doping) with a given *Analytical Testing Procedure* may not be mandatory for all *Laboratories*.

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possibility to submit the sample, as identified by the Agency, to Further Analysis. Results from any such analysis shall be reported to, and in a form designated by, the Agency and have the same validity and consequences as any other analytical result.

Rule 6321. 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;[24]

(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;

(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;

(7) Results from Initial Testing Procedures are not required to consider the associated MU, unless otherwise specified; 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 6322. 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

[24] Unless the "A" *Sample* cannot be used for the *Initial Testing Procedure(s),* see Rule 6317

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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; and

(4) All batches undergoing a Confirmation Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis.

Rule 6323. 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 6324. "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.[25] At this point, the link between the sample external Protocol as shown in the sample container and the Laboratory internal sample Protocol shall be verified.

(b) *Target Analyte(s)*. If the presence of more than one (1) Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method is detected by the Initial Testing Procedure(s), the Laboratory shall confirm as many of the Presumptive Adverse Analytical Findings as reasonably possible (such decision should consider the volumes available in the "A" and "B" samples). The confirmation(s) shall prioritize the identification 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.

(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

[25] Unless the "A" *Sample* cannot be used for the *Initial Testing Procedure(s),* see Rule 6317.

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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 the relevant Technical Document, Technical Letter or in consideration of Laboratory Guidelines.

(2) For Non-Threshold Substances with Minimum Reporting Levels as specified in the TD, 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 the TD, at an estimated concentration greater than the Minimum Reporting Level, unless there is justification for reporting the finding at levels below the Minimum Reporting Level (e.g., if the analysis forms part of an ongoing investigation).

(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 the TD, applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance or its Metabolite(s) or Marker(s) and their quantitative determination in the sample at a level exceeding the value of the relevant Decision Limit, which is specified in the TD DL or other applicable Technical Document(s) or Laboratory Guidelines.

(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 two (2) "A" Sample Aliquots, unless otherwise specified. If there is not enough sample volume to analyze two (2) Aliquots, the maximum number of Aliquots that can be prepared shall be analyzed.

(3) By determining that the test result exceeds the Decision Limit, the quantitative Confirmation Procedure establishes that the Threshold Substance or its Metabolite(s) or Marker(s) is present in the sample at a level greater than the Threshold, with a statistical confidence of at least 95% (for more information, refer to the TD DL).

(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 (endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

Rule 6325. "B" Sample Procedure.

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(a) *Testing Laboratory*. The "B" Sample Procedure may be performed in a different Laboratory from the "A" Sample Procedure if the Covered Person and/or Agency so elects, otherwise it will be analyzed in the A Sample Laboratory.

(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 shall inform the Laboratory, in writing, within fifteen (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 their 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, either upon the request of the Covered Person in accordance with the Protocol or the Agency, it shall be performed as soon as possible after the Agency has provided such notice to the Laboratory.

(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 and/or inadequately delay the decision-making process in the given circumstances (e.g., and without limitation, during or in view of a Covered Horserace requiring rapid completion of the sample analysis).

(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.[26]

(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. 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 and that the "B" sample was properly resealed.

(d) *Target Analyte(s)*. If more than one (1) Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method has

[26] Unless the "B" *Sample* cannot be used, see Rule 6317.

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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, the Laboratory shall conduct an internal investigation of the causes of the discrepancy between the "A" and "B" sample results.[27]

(g) *"B" Sample Procedure for Non-Threshold Substances and exogenous Threshold Substances*. For Non-Threshold Substances (including those with Minimum Reporting Levels as specified in the TD) and exogenous Threshold Substances, the "B" sample results shall only confirm the presence of the Prohibited Substance(s) or its Metabolite(s) or Marker(s) identified in the "A" sample (in compliance with the TD) for the Adverse Analytical Finding to be valid, unless otherwise specified. 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 the TD), 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 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.

(2) Quantitative "B" Sample Procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (e.g., concentrations, chromatogram areas) or the ratio/score calculated from the mean(s) of the measured analytical values of two (2) "B" sample aliquots, unless otherwise specified. If there is not enough sample

[27] *Target Analytes* [e.g., parent compound, *Metabolite(s)*, *Maker(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*.

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volume to analyze two (2) aliquots, the maximum number of Aliquots that can be prepared shall be analyzed.

(3) For Threshold Substances or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Finding decisions for the "B" sample results may also be based on the application of any Fit-for-Purpose Analytical Testing Procedure that establishes the exogenous origin of the Prohibited Substance and/or its Metabolite(s) or Marker(s). Atypical Findings may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

Rule 6326. 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 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, which were previously reported as Adverse Analytical Findings. Any Prohibited Substance or Prohibited Method detected, which was prohibited at the time of sample collection, shall be reported.

(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 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 ESL, Technical Documents, 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) and/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, and/or the scope of the further analysis restricted

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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 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 6329).

(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 two fractions, in accordance with Rule 6317.

(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.[28] If applicable, a "B" confirmation shall be decided and performed in accordance with Rule 6329.

(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 or hair (including whole blood, plasma or serum).

Rule 6327. Assuring the Validity of Analytical Results.

(a) The Laboratory shall monitor its analytical performance and the validity of test results by operating quality control schemes, which are appropriate to the type and frequency of Analytical Testing performed by the Laboratory. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.

(b) All quality control procedures shall be documented by the Laboratory. The range of quality control activities include, but are not limited to:

(1) Use of appropriate quality control samples (QCs).

[28] 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*).

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(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.

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(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.

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(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 and/or double-blind) introduction of the iQAS samples and management of the iQAS results (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, specification of their auditing activities, as well as for management of the internal audit conclusions (reviewing and follow-up of nonconformities).

(ii) Internal audit responsibilities may be shared amongst personnel provided that any Laboratory staff member does not audit their 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 6328. Results Management.

(a) *Review of Results*. The Laboratory shall conduct a minimum of one (1) independent review of all Initial Testing Procedure raw data and results. The review process shall be recorded.

(b) A minimum of two (2) Certifying Scientists shall conduct an independent review of all Adverse Analytical Findings and Atypical Findings before a test result is reported. Evidence of the review and approval of the analytical run/batch shall be recorded.

(c) *Second Opinion.* The Laboratory may request a second opinion from other Laboratory(-ies), upon approval by 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 Letters, required by the Agency from certain Laboratory(-ies) for all or for specific Analytical Testing Procedures under certain conditions (e.g., following the recent obtaining of HEAL accreditation or after a period of Suspension or Analytical Testing Restriction), or requested at the discretion of the Laboratory (e.g., for firstly detected Analytes or for difficult to interpret findings). In any case, the request for a second opinion shall be made in writing and the second opinion received shall be recorded as part of the Sample's documentation. Any transfer of data and information necessary for the second opinion shall be made securely and respecting the confidentiality of the analytical data and any other information. 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);

(7) Assessment of the existence of significant data or information that would cast doubt on or refute the Laboratory findings;[29]

(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.

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[29] The *Laboratory* should consider the prevailing scientific knowledge regarding, for example, the possibility of *sample* or *aliquot* contamination, the presence of analytical artifacts, the possible natural occurrence of the *Analyte* at low concentrations, microbial or chemical degradation, the detection of *Metabolites* which may be common to non-prohibited substances or the absence of characteristic Phase-I or Phase-II *Metabolites*.

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(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 as set forth in and limited by the TD.

(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) Laboratory Documentation Packages and Certificates of Analysis shall be in compliance with the TD LDOC. Laboratories are not required to produce a Laboratory Documentation Package for a Sample in which no Prohibited Substance or Prohibited Method or their Metabolite(s) or Marker(s) was detected, unless requested by an adjudication body as part of a Results Management process or Laboratory disciplinary proceedings.

(g) *Confidentiality of the Analytical Data and Covered Person and/or Covered Horse's Identity.*

(1) The Laboratory shall not make any attempt to identify a Covered Person linked to or the Covered Horse that has provided a sample.

(2) Information sent by a facsimile is acceptable provided that the correct facsimile number is verified prior to transmission and the receipt is verified after the facsimile has been transmitted.

(3) Secure emails or documents shall be used for reporting or discussion of Adverse Analytical Findings or Atypical Findings if the Covered Person or Covered Horse can be identified or if any information regarding the identity of the Covered Person or Covered Horse is included.

Rule 6329. Reporting Test Results.

(a) *Reporting Times*[30].

(1) Reporting of all "A" sample results shall occur to, and in a form designated by, the Agency no later than ten days (10) days from receipt of the sample. The reporting time required for specific occasions may be substantially less than ten (10) days. The reporting time may be altered by agreement between the Laboratory and the Agency. The Agency shall be informed of any delay in the reporting of "A" sample results.

(2) In order to expedite the results management process, an Abbreviated Laboratory Documentation Package shall be provided at the time of reporting an Adverse

[30] This includes confirmatory analysis

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Analytical Finding to the Agency unless the Agency indicates an Abbreviated Laboratory Documentation Package is not necessary. The Laboratory Documentation Packages or Certificates of Analysis shall be provided by the Laboratory only to the Agency upon request and shall be provided as soon as practicable and no later than five (5) days of the request, unless a different deadline is agreed upon with the Agency.

(b) *Reporting Requirements.*

(1) The Laboratory shall record the test result for each individual sample from the Agency to, and in a form designated by, the Agency.

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(2) When reporting test results to, and in a form designated by, the Agency, the Laboratory shall include, in addition to the mandatory information stipulated to, and in a form designated by, the Agency, in the relevant Technical Document(s) or Technical Letter(s), and in the ISO/IEC 17025 standard, the following:

(i) The Specific Gravity of the sample, if applicable (Initial Testing Procedure and "A" and "B" Confirmation Procedures);

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(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);[31]

(iii) Specific tests performed, in addition to the Laboratory routine Analytical Testing menu (e.g., EPO, bisphosphonates, hGH);

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(iv) Any irregularities noted on samples.

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(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 also 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.

[31] The *Laboratory* shall have a policy regarding the provision of opinions and interpretation of data. An opinion or interpretation may be included in the *Agency's Test Report* provided that the opinion or interpretation is clearly identified as such. The basis upon which the opinion has been made shall be documented. An opinion or interpretation may include, but not be limited to, recommendations on how to use results, information related to the pharmacology, metabolism and pharmacokinetics of a substance, whether the observed results may suggest the need for additional investigations regarding potential environmental contamination causes and/or *Further Analysis* and whether an observed result is consistent with a set of reported conditions.

(e) Any Sample received at the Laboratory and not subject to Analytical Testing for a valid, documented reason (as instructed by or agreed with the Agency) such as sample irregularities, intermediate samples of a Sample Collection Session, etc. (see Rule 6315).

(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) and/or its Metabolite(s), or Marker(s) of the Use of Prohibited Substance(s) or Prohibited Method(s) present (i.e., identified, as per the TD) in the sample and in accordance with the reporting requirements established in the TD.

(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, which has not been validated for quantitative purposes.

(2) "B" Sample Test Report.

(i) For Non-Threshold Substances, irrespective of whether they have a Minimum Reporting Level, the Laboratory result for the "B" sample shall only establish the presence (i.e., the identity) of the Prohibited Substance(s) or its Metabolite(s) or Marker(s) in accordance with the applicable Technical Document(s). The Laboratory is not required to quantify or estimate the concentration of such Prohibited Substance, or its Metabolite(s) or Marker(s).

(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 or 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 6330. 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 set requirements.

(b) Any nonconformities in Analytical Testing shall be recorded and kept as part of the documentation of the sample(s) involved.

(c) *Risk Minimization.* Laboratories shall take corrective actions in accordance with ISO/IEC 17025 for Corrective Action Investigation and Reporting.

(d) When conducting a corrective action investigation, the Laboratory shall perform and record a thorough Root Cause Analysis of the nonconformity.

(e) *Improvement.* The Laboratory shall maintain, and when appropriate improve, the effectiveness of its Management System in accordance with ISO/IEC 17025.

Rule 6331. Complaints.

Complaints shall be handled in accordance with ISO/IEC 17025.

Rule 6332. Storage of Samples.[32]

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

(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 three (3) months after reporting the final analytical result to the Agency, and may be discarded after this time, unless the long-term storage of the sample(s) has been requested, in writing or electronically, by the Agency and unless the Agency requests the Laboratory retain the sample for a longer period.[33]

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

(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 six (6) months after reporting the final analytical result (for the "A" or the "B" sample, as applicable to, the Agency and shall not dispose without approval by the Agency.

(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 6332) that the analysis of a urine sample is challenged, disputed or under investigation, the Laboratory shall retain both the "A" and "B" samples until further notice by the Agency, as applicable.

(b) *Storage of Blood Samples*.

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

(i) All serum or plasma samples retained for storage in the Laboratory shall be stored frozen according to established protocols in a secure location under continuous chain of

[32] [32] In this section 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*.

[33] 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*. Any *Further Analysis* on these *Samples* will require the approval of the *Agency*. The maximum storage period is ten (10) years after the sample collection date.

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custody. The Laboratory shall keep all chain of custody and other records (either as hard-copy or in digital format) pertaining to those samples.

(ii) Serum/plasma "A" and "B" samples without an Adverse Analytical Finding or Atypical Finding: The Laboratory shall retain the serum/plasma "A" and "B" samples without an Adverse Analytical Finding or Atypical Finding for a minimum of three (3) months after reporting the final analytical result to the Agency, if the long-term storage of the sample(s) has been requested by the Agency and unless the Agency requests the Laboratory retain the sample for a longer period.

(iii) Serum/plasma "A" and "B" samples without an Adverse Analytical Finding or Atypical Findings, analyzed only for TCO2 shall be retained for a minimum of one (1) month, unless otherwise requested by the Agency.

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

(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 six (6) months after reporting the final analytical result (for the "A" or the "B" sample, as applicable) to the Agency[34] and shall not dispose without approval by the Agency.

(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 6332) 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 one (1) month after reporting the final analytical result to the Agency.

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

(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 three (3) months after

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[34]If the "B" *Sample Confirmation Procedure* is not performed, the *Laboratory* may dispose of both the "A" and "B" whole blood *Samples* three (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 three (3) months after reporting the "B" *Sample* analytical result.

reporting the final analytical result (for the "A" or the "B" Sample, as applicable) to the Agency and shall not dispose without approval by the Agency.

(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 6332) 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.

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

(d) *Storage of Other Samples*. All other samples shall be stored in optimal conditions based on the available information applicable to the sample type, and at the direction of the Agency. They shall be stored in a secure location under continuous chain of custody.

(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 6326 and 6332.

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

(3) Laboratories as Sample Custodians:

(i) The Laboratory shall ensure that samples are stored according to established protocols in a secure location in the Laboratory's permanent controlled zone and under continuous chain of custody. The written request from the Agency for long-term storage of samples shall be properly documented.

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

(iii) If sample(s) are to be transported for storage at a location outside the secured area of the Laboratory that first analyzed the sample(s), the Laboratory shall secure the "A" sample(s) to be shipped either by re-sealing individual "A" Sample container(s) with a tamper-evident sealing system, which has similar capabilities for security and integrity as the original

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sealing system, or by sealing the box in which the sample(s) are shipped in a manner that maintains sample integrity and chain of custody.[35]

(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 6326.

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

(4) The Agency as Sample Custodians:

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

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

(iii) The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to all samples transferred for long-term storage for the duration of sample storage, either as hard-copy or in digital format. In addition, the

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[35]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.

Laboratory may retain sample analytical data which would allow retrospective analysis of such data. The Laboratory shall transfer the sample's external chain of custody and other non-analytical records to the Agency, either as originals or copies, immediately or upon request.

Rule 6333. 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 (see Protocol). Only after anonymization, may a sample or aliquot be used for:

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

(2) 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 6333 is subject to the following conditions:

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

(2) The Laboratory must not make any attempt to re-identify a Covered Person and/or Covered Horse from samples or aliquots used for the purposes of this Rule 6333 or data arising from any research or quality assurance analysis;

(3) The Laboratory must consult the applicable national regulations, guidance, or authorities to determine whether a study shall be considered as falling under paragraphs (d)(1) or (d)(2) of Rule 6333;[36]

(4) In the event the Laboratory wishes to transfer sample(s) or aliquots to be used for the purposes of this Rule 6333 to another Laboratory or a third-party research institution or group, or wishes to partner with another Laboratory or research institution or group for the purpose

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[36] If the *Laboratory* is unsure whether a study can proceed without consent after consulting the foregoing sources, the *Laboratory* shall consult with the *Agency*.

of an paragraph (d)(1) of this Rule 6333 study, the Laboratory shall subject the receiving party to the conditions described in this Rule 6333 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.

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Rule 6334. Management Requirements.

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

(b) *Management Reviews*. Management reviews will be conducted to meet the requirements of ISO/IEC 17025.

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

(d) *Control and Storage of Technical Records*. The Laboratory shall keep a copy of all Sample records to the extent needed to produce Laboratory Documentation Packages or Certificates of Analysis, in accordance with the Technical Document, in a secure storage until Sample disposal or anonymization.

(e) *Cooperation with the Agency.* Cooperation with the Agency shall be handled in accordance with ISO/IEC 17025.

(f) *Ensuring Responsiveness to the Agency*. The Laboratory Director or their designee shall:

(1) Ensure adequate communication with the Agency in a timely manner;

(2) Provide complete, appropriate and timely explanatory information as requested by the Agency;

(3) Report to the Agency any unusual circumstances or information with regard to Analytical Testing, patterns of irregularities in Samples, or potential Use of new substances;

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

(5) The Laboratory Director shall be familiar with the Protocol and the Prohibited List.

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

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

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

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

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

(5) Responding to any complaint submitted by the Agency concerning the Laboratory and its operation;

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

6400. EVALUATION OF LABORATORY EQAS.

Rule 6410. Penalties.

(a) The Agency shall inform a Laboratory in writing about the imposition of penalty, 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*.[37] 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.

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.

[37] 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, which were made by the *Agency*.

(b) A Corrective Action Reports related, for example, to nonconformities detected during the Agency Laboratory assessments, or to procedural or reporting nonconformities with the ESL, Technical Documents or Technical Letters, or unsatisfactory performance in the analysis of EQAS samples (not related to a false Adverse Analytical Finding or false Negative Finding), shall be submitted to the Agency within thirty (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 in the routine operations of the Laboratory immediately.

(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. 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 shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within seven (7) days, or as otherwise agreed with the Agency.

(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.

If 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.

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Rule 6440. Evaluation of EQAS Results.

(a) Satisfactory EQAS performance in single EQAS round[38] and over a consecutive twelve (12)- month period[39] is necessary for maintaining HEAL accreditation.

(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.[40]

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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) The results for any Non-Threshold Substance or its Metabolite(s) or Marker(s) at concentrations below (<) 50% of the applicable MRPL in an EQAS sample shall report their finding(s) if the analyses are compliant with its validation data, SOPs, the ESL and the TD IDCR. Laboratories unable to report such substance(s) are encouraged, on receipt of the EQAS report, to consider re- assessment of their Analytical Testing Procedure.

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).

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[38] 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*.

[39] The twelve (12)-month period is defined as the most recent consecutive twelve (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.

[40] 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*.

(b) A Laboratory is to achieve a satisfactory statistical evaluation of quantitative results reported based on the mean of two (2) replicate determinations. The overall evaluation of the quantitative performance is based on the criteria indicated in the effective version of the TD DL or other relevant Technical Document, Technical Letter or Laboratory Guidelines.

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(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 (1) decimal place) for the Laboratory's quantitative result is < 3.0.

(d) *Unsatisfactory Quantitative Result for Threshold Substances* (absolute z-score ≥ 3.0).[41] The Laboratory shall provide the Agency with a Corrective Action Report for an unsatisfactory quantitative result.

(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, three (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

[41] The z–score is calculated according to the following formula and truncated to one (1) decimal place:

$$z = \frac{\bar{y} - \hat{y}}{\delta}$$

Where: $\bar{y}$ is the mean value of the *Laboratory*'s replicate determinations; $\hat{y}$ is the assigned value (reference, nominal or consensus value, as applicable); δ is the target standard deviation (*e.g.*, u_{c_Max} or robust *Reproducibility* s_R of results from all participant *Laboratories*).

example, The Laboratory may be required by the Agency to analyze EQAS samples and/or to review the relevant analytical results and to re-analyze any relevant and available samples previously reported as Adverse Analytical Findings during the preceding twelve (12) months (or during a period otherwise determined by the Agency) within seven (7) days (unless informed otherwise by the Agency). Depending on the nature of the error that caused the false Adverse Analytical Finding or false Negative Finding, this re-analysis may be limited to one Analyte, a class of Prohibited Substances or Prohibited Methods, or may include any Prohibited Substance or Prohibited Method. A statement signed by the Laboratory Director shall record this re-analysis.[42]

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(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 6311.

(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.[43]

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 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 six (6) months or until such a time when the Laboratory can satisfactorily correct all the issues identified. If the Laboratory under Suspension

[42] 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*.

[43] 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.

fails to satisfy performance criteria during an extended period of Suspension (beyond the initial six (6) months), then the Agency may Revoke the Laboratory's accreditation.

(c) Laboratories under an Analytical Testing Restriction remain operational (except for the activity(-ies) under the Analytical Testing Restriction) and, therefore, are evaluated during the Analytical Testing Restriction as any other, fully operational Laboratory.

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 thirty (30) days prior to the end of the Suspension period (unless otherwise indicated by the Agency). Failure to do so will preclude the laboratory from participating in the probationary EQAS.

(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 as candidate laboratories and are subject to provide the applicable accreditation fee and the required 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 the purpose described in Protocol. The Agency shall retain the right to request analysis or further analysis, at its expense, as permitted by Protocol.[44]

(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,

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[44] If *Laboratory* nonconformities are revealed with respect to the *Analytical Testing* of any Sample, the *Agency* retains the right to recover the expenses incurred in connection with the analysis or *Further Analysis* of the *Samples* from the *Laboratory*.

the Agency shall be responsible for maintaining proper sample chain of custody documentation and the safety and integrity of the samples until receipt by the other Laboratory(-ies).

(c) The Agency may also require that the Laboratory transfer the samples. In such situations, the Laboratory shall be responsible for maintaining proper chain of custody documentation for all transferred samples and the safety and integrity of the samples until receipt by the receiving Laboratory(-ies).

(d) In connection with its monitoring of Laboratory performance, the Agency may direct further analysis of a sample which has resulted in a Protocol anti-doping rule violation without consent of the Covered Person or approval from an adjudication body as provided in Protocol.

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 6333, 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.[45]

6500. WITHDRAWAL OF HEAL ACCREDITATION.

Rule 6510. Withdrawal of HEAL Accreditation.

(a) A Laboratory's HEAL accreditation may be Suspended or Revoked, or subject to an Analytical Testing Restriction, whenever the Laboratory fails to comply with the ESL, 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 a noncompliance with the ESL, 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 ESL.

(a) Noncompliance with the ESL that may lead to an Analytical Testing Restriction, Suspension, Revocation of HEAL accreditation, or other follow up measures include, but are not limited to:

(1) Suspension, or withdrawal of ISO/IEC 17025 accreditation;

[45] A transfer of *Samples* with *Negative Findings* shall apply only to *Samples* collected by the *Agency.*

(2) Failure to establish or maintain administrative and operational independence as described in paragraph (b)(7) of Rule 6110;

(3) Failure to analyze the minimum number of Samples indicated in paragraph (i) of Rule 6130;

(4) Reporting of false Adverse Analytical Findings or false Negative Findings;[46]

(5) Failure to implement a Technical Document or Technical Letter by the effective date without prior approval by the Agency;

(6) Failure to comply with any of the requirements or standards listed in the ESL, Technical Documents or Technical Letters;

(7) Noncompliance with results reporting timelines in Rule 6329);

(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 ESL, Technical Document, or Technical Letter 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;

(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, 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 a month) to the Agency;

(2) Failure to appoint a permanent Laboratory Director or other senior management positions (e.g., Quality Manager) within a reasonable timeline;

(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;

[46] *Agency* decisions are made in consideration of the number of false analytical findings reported by the Laboratory, irrespective of whether the Laboratory has satisfactorily corrected the noncompliance.

(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 enquiry 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 or 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 of Analytical Testing Restriction, if applicable; and

(4) Any corrective actions or other follow up requirements.

Rule 6540. Effective Date and Appeals.

(a) A Revocations, Suspension, or Analytical Testing Restriction is effective immediately upon receipt of notification of the 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 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 the Laboratory's HEAL accreditation is reinstated following a suspension.

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Rule 6560. Consequences of 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 for Race Day or Out-of-Competition samples received by the Laboratory, the Agency may impose an Analytical Testing Restriction for that class of Prohibited Substance(s) or Prohibited Method(s) or for the specific Analytical Testing Procedure in which the noncompliance(s) occurred.

(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 shall transfer[47] 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, or 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, or 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) for the "A" Confirmation Procedure to be performed again and for the performance of the "B" Confirmation Procedure, if applicable.

(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) for Further Analysis, as determined by the Agency. These re-analyses may

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[47] The *Laboratory* under *Analytical Testing Restriction* shall contact the *Agency* to arrange for the transfer of the relevant *Samples* to subcontracted *Laboratory*(-ies), chosen by the *Agency*, within thirty (30) days of being notified of the *Analytical Testing Restriction* decision. All associated costs shall be borne by the *Laboratory* under *Analytical Testing Restriction*.

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) chosen 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) 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, or 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)].

(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, or samples which were undergoing "A" or "B" Confirmation Procedures at the time of the suspension;

(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 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 three (3) months or have been placed in long-term storage upon request by the Agency.

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(2) These samples shall be kept in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions. The Laboratory shall inform the Agency of such actions including the provision of the Sample Protocols.

(3) If the suspension was caused by the reporting of false Negative Finding(s), and further investigation reveals that other Negative Finding(s) had been reported by the Laboratory, the Laboratory shall inform the Agency. In such cases, both the "A" and "B" containers of the relevant samples shall be transferred to another Laboratory(-ies) for Further Analysis, as determined by the Agency. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the requested Analytical Testing menu or be limited to the class of Prohibited Substances or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by the Agency.

(4) 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) 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) for the repetition of the Initial Testing Procedure(s) and, if needed, the performance of Confirmation Procedures. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the requested Analytical Testing menu or be limited to the class of Prohibited Substances or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding, as determined by the Agency.

(iii) If the reason for the suspension was not related to the reporting of false Negative Findings and the Initial Testing Procedures had produced negative results, the Sample(s) shall be reported to the Agency as Negative Finding(s). These Samples shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions until further notice by the Agency. The Laboratory shall inform the Agency of such actions including the provision of the Sample Protocols.

(5) 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 Protocols.

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(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) 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" amples transferred to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.

(6) Samples which had been received at the Laboratory but had not been opened yet at the time of the Suspension:

(i) These samples shall be kept sealed in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until transfer to another Laboratory(-ies) for Analytical Testing.

(7) Samples for which "A" or "B" Confirmation Procedures had been completed, but results of analysis had not been reported by the suspension date, or samples which were undergoing "A" or "B" Confirmation Procedures at the time of the suspension:

(i) Both the "A" and "B" samples shall be transferred to another Laboratory(- ies) for the repetition of the "A" and, if applicable, the "B" Confirmation Procedures.

(8) 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) 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).

(b) A laboratory whose HEAL accreditation has been revoked shall arrange the transfer of samples in the laboratory's custody to a Laboratory(-ies) chosen by the Agency, respectively, within thirty (30) days of being notified of the decision revoking its HEAL accreditation. In such circumstances, the Samples to be transferred shall be selected the Agency. The laboratory transferring the Samples shall inform the Agency and provide the relevant Sample Protocols and the chosen Laboratory(-ies). In addition, the revoked laboratory shall assist with the transfer of the relevant sample data and records to the Laboratory(-ies) that have been selected to receive the Samples.

(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 6332, 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).

Rule 6563. Reinstatement of Suspended Accreditation or Lifting of the 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, 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 has been the subject of an Analytical Testing Restriction has not satisfactorily corrected the ESL, 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 ESL, 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 Analytical Testing Restriction may be further extended or the Laboratory's accreditation shall be revoked, as determined by the Agency. The ssuspension or Analytical Testing Restriction period may be extended up to an additional six (6) months, if the Laboratory provides justifiable explanation(s) for the delay, as determined by the Agency, in addressing the conditions to lift the suspension or Analytical Testing Restriction (including the submission of satisfactory corrective actions).

(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 ESL, Technical Document, or Technical Letter noncompliance(s) have been corrected, the Laboratory's accreditation shall be re-instated or the Analytical Testing Restriction may be lifted by decision of the Agency.

(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.

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(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 ESL noncompliance(s) and not having been subject to an Analytical Testing Restriction or suspension or revocation of its HEAL accreditation.

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(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 taken to cease its operations and no later than three (3) months prior to the date on which its decision shall take effect. The Laboratory shall also take all necessary measures to notify all its clients of the decision to cease its operations and to arrange, in consultation with its clients, to transfer Samples to another Laboratory(-ies) in accordance with 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 six (6) months, with one possible extension of up to six (6) months (as determined by the Agency). If the Laboratory is unable to resume its Analytical Testing operations within a twelve (12)- month period, the Agency shall revoke the Laboratory's accreditation, unless otherwise approved by the Agency.

(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 to receive the samples.

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6600. CODE OF ETHICS FOR LABORATORIES AND RESEARCH AND DEVELOPMENT ACTIVITY REQUIREMENTS.

Rule 6610. Code of Ethics for Laboratories.

(a) *Confidentiality*. Directors of Laboratories, their delegates and all Laboratory staff shall respect and comply with ESL and Protocol.

(b) *Research in Support of Doping Control*.

(1) Laboratories shall participate in research programs, provided that the Laboratory Director is satisfied with their bona fide nature and the program(s) have received proper ethical approval, if applicable. The Laboratory shall not engage in any research activity that undermines or is detrimental to the purposes of the Act.

(2) The Laboratories are expected to develop a research and development program to support and expand the scientific foundation of Doping Control. This research may consist of the development of new methods or technologies, the pharmacological characterization of a new doping agent, the characterization of a masking agent or method, and other topics relevant to the field of Doping Control.

(3) Research on Equine (and other animal species) Subjects.

(4) Laboratories shall follow institutional animal care and use guidelines and requirements regarding the use of animal subjects in research.

(5) Covered Horses who may undergo Doping Control Testing shall not be the subjects of drug administration studies that include Prohibited Substances or Prohibited Methods.

(c) *Controlled Substances*. The Laboratories are expected to comply with the relevant and applicable national laws regarding the handling, storage and discarding of controlled (illegal) substances.

(d) *Analysis*. The Laboratory 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*. The 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 Equine 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 6322.

(f) *Analytical Testing for Covered Persons or those acting of their behalf*. Laboratories shall not accept samples directly from individual Covered Persons or from individuals or organizations acting on their behalf.

(g) *Other Analytical Activities*.

(1) The Laboratory shall not provide analytical services in a Doping Control adjudication, unless specifically requested by the Agency or an adjudication body.

(2) The Laboratory shall not engage in analyzing commercial material or preparations (e.g., dietary or herbal supplements), unless:

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(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 their representative, the Laboratory may conduct the analysis if agreed by the Agency, which may also specify conditions that must be followed prior to or during the analysis (e.g., verification of original sealed packages, product batch number).

(3) The Laboratory shall not provide results, documentation or advice that, in any way, could be used as an endorsement of products or services.

(4) Analytical activities performed outside the Act will not fall under Agency-accredited status of the laboratory and shall not negatively affect the Analytical Testing of samples from the Agency.[48]

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(h) *Sharing of Knowledge*[49]

(1) When information on new doping substance(s), method(s), or practice(s) is known to the Laboratory, such information shall be shared with the Agency within sixty (60) days. When possible, the Laboratories shall share information with the Agency regarding the detection of potentially new or rarely detected doping agents as soon as possible. Immediately after having been notified of the Use of a new substance or method as a doping agent, the Agency will inform all Laboratories.

(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 Anti-Doping and Medication Control Program Contemplated in the Act and to Avoid any Detrimental Conduct.*

(1) The personnel of Laboratories shall not engage in conduct or activities that undermine or are detrimental to the anti-doping and medication control program contemplated in the Act. Such conduct could include, but is not limited to, fraud, embezzlement, perjury, etc. that would cast doubt on the integrity of the anti-doping and medication control program.

(2) All employees of Laboratories shall strictly respect the confidentiality of Analytical Testing results, as well as of all other Laboratory, including information provided by the Agency under confidentiality.

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[48] *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.

[49] Sharing of knowledge can occur in various ways, including but not limited to directly communicating with the *Agency*, participating in scientific meetings, publishing results of research, sharing of specific details of *Analytical Methods*, working with the *Agency* to produce and/or distribute new *Reference Material(*s) or Reference *Collection(s)* or disseminating information regarding the chromatographic behavior and mass spectra of the *Analytes*.

(3) No employee or consultant of Laboratories shall provide counsel, advice or information to Covered Persons or others regarding techniques or methods used to mask or avoid detection of, alter metabolism of, or suppress excretion of a Prohibited Substance or its Metabolite(s), or Marker(s) of a Prohibited Substance or Prohibited Method in order to avoid an Adverse Analytical Finding.

(4) No employee or consultant of Laboratories shall provide information about a Test Method to a Covered Person, or from individuals or organizations acting on their behalf, which could be used to avoid the detection of doping. They will instead be referred to the Agency.

(5) No staff of Laboratories shall assist a Covered Person in avoiding collection of a representative Sample (e.g., advice on masking strategies or detection windows). [This 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 a staff member of a Laboratory is requested to provide evidence in anti-doping proceedings, they are expected to provide independent, scientifically valid expert testimony.

(7) The Laboratory shall not issue any statements related to its analytical processes or findings, unless otherwise provided in Protocol. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be the sole responsibility of the responsible the Agency.

(j) *Breach and Enforceability*.

(1) A failure to respect any of the provisions of this Code of Ethics may result in the Laboratory being subject to Disciplinary Proceedings instituted by the Agency to either suspend or revoke its HEAL accreditation or its Agency approval, as applicable.

(2) In addition, a failure to respect any of the provisions of this Code of Ethics may result in staff of the Laboratory being subject to disciplinary action by the Laboratory, respectively, resulting in consequences beyond those stipulated under the ESL, including potential termination of employment or, where applicable, the imposition of criminal charges.

Rule 6620. Research and Development Activity Requirements.

(a) The Laboratory must receive a minimum score of ten (10) points annually.

(1) Five (5) points for each Peer-Reviewed Manuscript;

(2) Five (5) points for the production of educational materials

(3) Five (5) points for each Funded Research Project

(4) Five (5) points for hosting hands-on training workshop for all HEAL labs.

(5) Two (2) points for each Laboratory (Internal) Method Development.

(b) The validation or implementation of established anti-doping methods with only minor adjustments, or repetition of research previously published or presented by others, is not sufficient to be considered as a research and development activity.

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