

~~WORLD ANTI-DOPING CODE~~



The World Anti-Doping Code

INTERNATIONAL STANDARD FOR LABORATORIES

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International Standard for Laboratories

The World Anti-Doping Code International Standard for Laboratories (ISL) is a mandatory *International Standard* developed as part of the World Anti-Doping Program.

The International Standard for Laboratories first came into effect in November 2002. Further revisions were made after that date.

The enclosed International Standard for Laboratories was approved by the WADA Executive Committee on ~~11~~15 May ~~2016~~2019. The effective date of ISL version ~~9~~10.0 is ~~02 June 2016~~01 November 2019.

The official text of the ISL shall be maintained by WADA and shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

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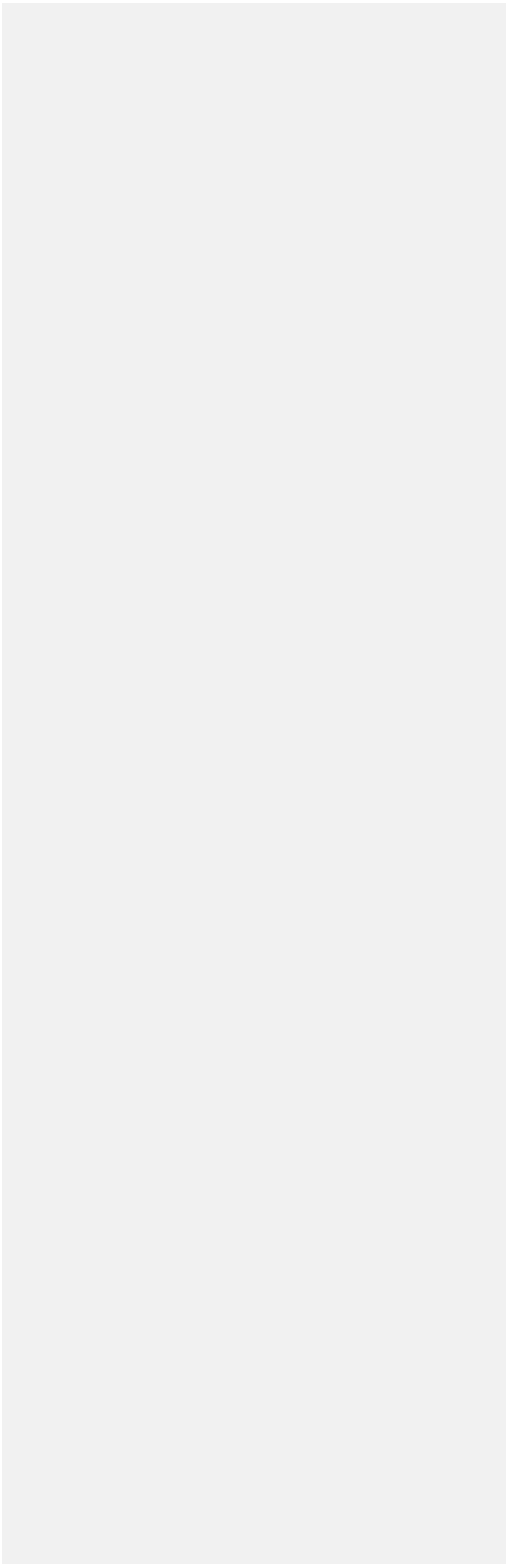


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PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS

1.0 Introduction, Scope and References

The main purpose of the International Standard for Laboratories (ISL) is to ensure laboratory production of valid test results and evidentiary data and to achieve uniform and harmonized results and reporting from all Laboratories.

The ISL includes requirements for obtaining and maintaining WADA accreditation of Laboratories, operating standards for laboratory performance and a description of the accreditation process.

WADA will publish, from time to time, specific technical requirements in a Technical Document. Implementation of the technical requirements described in the Technical Documents is mandatory and shall occur by the effective date specified in the Technical Document. Technical Documents supersede any previous publication on a similar topic, or if applicable, this document. The document in effect shall be that Technical Document whose effective date most recently precedes that of Sample receipt date. The current version of the Technical Document will be available on WADA's website. Technical Documents are posted on WADA's website when approved by the WADA Executive Committee and may be applied prior to the effective date for implementation.

The ISL, including all Annexes and Technical Documents, is mandatory for all Signatories to the Code.

1.1 The ISL and the World Anti-Doping Program

The World Anti-Doping Program encompasses all of the elements needed in order necessary to ensure optimal harmonization and best practice in international and national anti-doping programs. The main elements are:

- the Code (Level 1),
- International Standards (Level 2), and
- Models of Best Practice and Guidelines (Level 3).

In the introduction to the World Anti-Doping Code (Code), the purpose and implementation of the International Standards are summarized as follows:

"International Standards for different technical and operational areas within the anti-doping program have been and will be developed in consultation with the Signatories and governments and approved by WADA. The purpose of the International Standards is harmonization among Anti-Doping Organizations responsible for specific technical and operational parts of anti-doping programs. Adherence to the International Standards is mandatory for compliance with the Code. The International Standards may be revised from time to time by the WADA Executive Committee

after reasonable consultation with the *Signatories*, governments and other relevant stakeholders. *International Standards* and all revisions will be published on the WADA website and shall become effective on the date specified in the *International Standard* or revision.”

~~Compliance with an *International Standard*~~The main purpose of the *International Standard for Laboratories (ISL)* is to ensure that Laboratories and WADA-Approved Laboratories for the ABP report valid test results based on reliable evidentiary data, and to facilitate harmonization in Analytical Testing of Samples by Laboratories and in the analysis of ABP blood Samples by Laboratories and WADA-Approved Laboratories for the ABP.

The ISL sets out the requirements to be followed by Laboratories and WADA-Approved Laboratories for the ABP that wish to demonstrate that they are technically competent, operate within an effective Management System, and are able to produce forensically valid results. The ISL includes, *inter alia*, requirements for obtaining and maintaining WADA Laboratory accreditation and WADA laboratory approval for the ABP, operating standards for the performance of Laboratories and WADA-Approved Laboratories for the ABP and a description of the accreditation and approval processes.

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

1.2 This document sets out the WADA Laboratory Standards

WADA will publish specific technical requirements for in a Technical Document or Technical Letter. In addition, WADA may also provide Laboratories that wish, WADA-Approved Laboratories for the ABP and other stakeholders with specific technical guidance and advice in the form of Laboratory Guidelines or Technical Notes.

1.2.1 Technical Documents

- Technical Documents are issued to demonstrate that they are technically competent, operate and provide direction to the Laboratories, WADA-Approved Laboratories for the ABP and other stakeholders on specific technical or procedural issues. Technical Documents are modified and/or withdrawn by WADA as appropriate.

- Technical Documents are approved by the WADA Executive Committee and published on WADA's website. Once approved, a Technical Document supersedes any previous publication on a similar topic¹ and becomes an integral part of the ISL.
- Implementation of the requirements detailed in a Technical Document may occur prior to the effective quality management system, and are able to produce forensically valid results. ~~Doping Control~~ date for implementation specified in the Technical Document and shall occur no later than the effective date.²
- The implementation of the requirements of WADA Technical Documents into the Laboratory's and, if relevant to the analysis of ABP blood Samples, WADA-Approved Laboratory for the ABP's Management System is mandatory for obtaining and maintaining WADA accreditation or approval, respectively, and for the application of the relevant Analytical Testing Procedure(s) to the analysis of Samples.
- In cases when a newly approved version of a Technical Document lowers either the Decision Limit for a Threshold Substance or the reporting limit for a Non-Threshold Substance, 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.³

¹ WADA will provide guidance to Laboratories, WADA-Approved Laboratories for the ABP and other WADA stakeholders on what other standard(s) may be affected by a new Technical Document or Technical Letter in the Summary of Modifications that accompanies the publication of the revised version of the Technical Document or Technical Letter.

² A failure by a Laboratory or WADA-Approved Laboratory for the ABP to implement a Technical Document or Technical Letter after the effective date may result in the imposition of an Analytical Testing Restriction against the Laboratory for that particular Analytical Testing Procedure or a Suspension of the Laboratory's WADA accreditation, or a Suspension of the approval for the ABP, respectively, as determined by WADA.

Laboratories and WADA-Approved Laboratories for the ABP may implement a Technical Document as soon as it is approved by the WADA Executive Committee and published on WADA's website, provided that the requirements of the Technical Document have been implemented and documented in the Laboratory's or WADA-Approved Laboratory for the ABP's Standard Operating Procedure(s) [SOP(s)]. If a Laboratory or WADA-Approved Laboratory for the ABP is not able to implement a new Technical Document by its effective date, it shall inform its clients as soon as possible. The Laboratory or WADA-Approved Laboratory for the ABP shall also send a written request to WADA for an extension beyond the applicable effective date, providing the reasons for the delayed implementation of the Technical Document, any measures taken to ensure that Samples received in the Laboratory or WADA-Approved Laboratory for the ABP will be subject to Analytical Testing in compliance with the new Technical Document (for example, by subcontracting analysis to another Laboratory or WADA-Approved Laboratory for the ABP, as applicable), as well as plans for the implementation of the new Technical Document.

³ If the application of a newly approved Technical Document results in an Adverse Analytical Finding for a Sample collected before 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 (for example if

- The most recently approved Technical Document shall be applied to Analytical Testing of *Samples* if it would lead to a result that benefits the *Athlete* (e.g. increase of the Decision Limit for a Threshold Substance or of the reporting limit for a Non-Threshold Substance, establishment of more stringent identification criteria for chromatographic-mass spectrometric or electrophoretic 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.
- Subject to the above, the analysis of *Samples* or the review of analytical data may occur immediately once a Technical Document has been approved.

1.2.2 Technical Letters

- Technical Letters are issued in letter format on an *ad-hoc* basis in order to provide direction to the Laboratories, WADA-Approved Laboratories for the ABP and other stakeholders on particular issues on the analysis, interpretation and reporting of results for specific *Prohibited Substance(s)* and/or *Prohibited Method(s)* or on the application of specific Laboratory procedures. Technical Letters are modified and/or withdrawn by WADA as appropriate.
- Technical Letters are approved by the WADA Executive Committee and published on WADA's website. Technical Letters become effective immediately, unless otherwise specified by WADA⁴.
- Once approved, a Technical Letter supersedes any previous publication on a similar topic¹ and becomes an integral part of the ISL.
- The implementation of the requirements of relevant Technical Letters into the Laboratory's and, if relevant to the analysis of ABP blood *Samples*, WADA-Approved Laboratory for the ABP's Management System is mandatory for obtaining and maintaining WADA accreditation or approval, respectively, and for the application of the relevant Analytical Testing Procedure(s) to the analysis of *Samples*.

the Decision Limit for a Threshold Substance has been lowered in the newly approved Technical Document), 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 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, WADA shall make a time provision for implementation and specify an effective date for the Technical Letter.

If a Laboratory or WADA-Approved Laboratory for the ABP is not able to implement a new Technical Letter by its effective date, the Laboratory or WADA-Approved Laboratory for the ABP shall send a written request to WADA for an extension beyond the applicable effective date, providing the reasons for the delayed implementation of the Technical Letter, any measures taken to ensure that *Samples* received in the Laboratory or WADA-Approved Laboratory for the ABP will be subject to Analytical Testing in compliance with the new Technical Letter (for example, by subcontracting analysis to another Laboratory or WADA-Approved Laboratory for the ABP, as applicable), as well as plans for the implementation of the new Technical Letter.

1.2.3 Laboratory Guidelines

- Laboratory Guidelines are issued in order to provide direction to the Laboratories, WADA-Approved Laboratories for the ABP and other WADA stakeholders on new Analytical Methods or procedures approved by WADA. Laboratory Guidelines are modified and/or deleted by WADA as appropriate.
- Laboratory Guidelines are approved by the WADA Laboratory Expert Group (LabEG) and are published on WADA's website.
- Implementation of Laboratory Guidelines is not mandatory. However, Laboratories and WADA-Approved Laboratories for the ABP are encouraged to follow, to the fullest extent possible, the recommendations of best practice included in relevant Laboratory Guidelines.

1.2.4 Technical Notes

- Technical Notes are issued to Laboratories to provide detailed technical guidance on the performance of specific Analytical Methods or procedures.
- Technical Notes are approved by the WADA LabEG. Technical Notes are provided to Laboratories only and are not published on WADA's website.
- 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.

1.3 Sample Analysis

Sample analysis is part of the Analytical Testing process and involves the detection, identification, and in some cases demonstration of the presence greater than a threshold concentration or ratio of measured analytical values (e.g. concentrations, chromatogram peak height or area) of drugs and other substances in above a Threshold of Prohibited Substance(s) and/or their Metabolite(s), or Marker(s) of Use of Prohibited Substances or Prohibited Methods in human biological fluids or tissues as identified on the List of Prohibited Substances and Prohibited Methods (the Prohibited List).

Laboratories may undertake other forms of analysis, within subject to the limits provisions of the Code of Ethics, (see Annex A of the ISL), which are not under the scope of WADA Accreditation accreditation (e.g. Equine animal sports testing, Forensic forensic testing), clinical testing, drugs of abuse testing). Any such testing shall not be covered by WADA Accreditation the Laboratory's WADA accreditation and, therefore, shall not be subject to the requirements of the ISL, Technical Documents or Technical Letters. For the avoidance of doubt, Laboratory Test Reports, Certificates of Analysis or other documentation or correspondence shall not declare or represent that any such testing is covered under the Laboratory's WADA accreditation status.

WADA-Approved Laboratories for the ABP may undertake other forms of analyses, which are not within the scope of the WADA approval (e.g. forensic testing, clinical testing, drugs of abuse testing). For the

avoidance of doubt, Test Reports, Certificates of Analysis or other documentation or correspondence from WADA-Approved Laboratories for the ABP shall not state or represent that any such testing is covered under their WADA approval status.

1.4 Laboratory Accreditation Framework and Laboratory Approval for the ABP

The Laboratory accreditation framework consists of two main elements: Part Two of the ISL (the Laboratory accreditation requirements and operating standards) and Part Three (the Annexes).

- Part Two of the ISL describes the requirements necessary to obtain and maintain WADA accreditation and the procedures involved to fulfill these requirements (Section 4). It also includes the application of ISO/IEC 17025⁵ to the field of Doping Control (Section 5) and a description of the WADA External Quality Assessment Scheme (EQAS) (Section 6) as well as the procedures to evaluate the Laboratory EQAS and routine Analytical Testing performance by WADA (Section 7). The purpose of this section of the document is to facilitate the consistent application of ISO/IEC 17025 and ISL-specific requirements to Analytical Testing for Doping Control by Laboratories, as well as to facilitate the assessment of ISO/IEC 17025 and the specific WADA requirements for Doping Control by accreditation bodies that operate in accordance with ISO/IEC 17011. The International Standard also sets forth the requirements for Laboratories when adjudication results as a consequence of an Adverse Analytical Finding Laboratory compliance by Accreditation Bodies and WADA.

Section 4 of the ISL also describes the requirements necessary to obtain and maintain WADA approval for the ABP.

- Part Three of the ISL includes all Annexes. Annex A describes the WADA External Quality Assessment Scheme (EQAS), including performance criteria necessary to maintain WADA accreditation. Annexes A (Code of Ethics) and B describes (Procedural Rules) describe the ethical and legal standards required for continued WADA accreditation of the Laboratory. Technical Documents are issued, modified, and deleted by WADA from time to time and provide direction to the Laboratories and other stakeholders on specific technical issues. Once promulgated, Technical Documents become an integral part of the ISL. The incorporation of the provisions of the approved WADA Technical Documents into the Laboratory's quality management system is mandatory for WADA accreditation or continued approval of the laboratory for the ABP.

In order to harmonize the accreditation of Laboratories to the requirements of ISO/IEC 17025 and of WADA-Approved Laboratories for the ABP to the requirements of ISO/IEC 17025 or ISO 15189, as well as the WADA-specific requirements for accreditation, national accreditation bodies with approval, Accreditation Bodies are required to use the ISL, including the applicable Annexes and Technical

⁵ Effective version of ISO/IEC 17025.

Documents, Technical Letters and Laboratory Guidelines as reference documents in their assessment process.

Maintenance of a Laboratory's accreditation or approval by WADA is based on satisfactory performance in the WADA EQAS and routine testing. A Laboratory's Analytical Testing. The EQAS performance of Laboratories and WADA-Approved Laboratories for the ABP is also continually monitored by WADA and reviewed as part of their ISO-accreditation body/IEC 17025 or ISO 15189 Accreditation Body assessment process. Therefore a Laboratory's EQAS results, as applicable. Therefore, the Laboratory or WADA-Approved Laboratory for the ABP shall not be subject to challenge or to demands to produce Laboratory EQAS results data or related EQAS documentation by third parties.

Terms defined in the *Code*, which are included in this standard, are written in ~~italics~~ italics.
Terms, which are defined in the ISL or other International Standards, are underlined.

¹ Current version of ISO/IEC 17025

Other terms are used in the ISL and other WADA Laboratory standards as follows:

- "Shall" is used to indicate a mandatory obligation;
- "Should" is used to indicate a strong recommendation for best practice;
- "May" is used to indicate an optional practice or standard;
- "Can" is used to indicate a possibility or a capability.

2.0 Code Provisions

The following ~~articles~~Articles in the ~~Code~~ directly address the ISL:

Code ~~Article~~are addressed in the ISL:

- Code Art. 2 —ANTI-DOPING RULE VIOLATIONS

~~2.1— Presence of a Prohibited Substance or its Metabolites or Markers in an Athlete's Sample:~~

~~2.1.1— It is each Athlete's personal duty to ensure that no Prohibited Substance enters his or her body. Athletes are responsible for any Prohibited Substance or its Metabolites or Markers found to be present in their Samples. Accordingly, it is not necessary that intent, Fault, negligence or knowing Use on the Athlete's part be demonstrated in order to establish an anti-doping rule violation under Article 2.1.~~

~~[Comment to Article 2.1.1: An anti-doping rule violation is committed under this Article without regard to an Athlete's Fault. This rule has been referred to in various CAS decisions as "Strict Liability". An Athlete's Fault is taken into consideration in determining the Consequences of this anti-doping rule violation under Article 10. This principle has consistently been upheld by CAS.]~~

~~2.1.2— Sufficient proof of an anti-doping rule violation under Article 2.1 is established by any of the following: presence of a Prohibited Substance or its Metabolites or Markers in the Athlete's A Sample where the Athlete waives analysis of the B Sample and the B Sample is not analyzed; or, where the Athlete's B Sample is analyzed and the analysis of the Athlete's B Sample confirms the presence of the Prohibited Substance or its Metabolites or Markers found in the Athlete's A Sample; or, where the Athlete's B Sample is split into two bottles and the analysis of the second bottle confirms the presence of the Prohibited Substance or its Metabolites or Markers found in the first bottle.~~

~~[Comment to Article 2.1.2: The Anti-Doping Organization with results management responsibility may, at its discretion, choose to have the B Sample analyzed even if the Athlete does not request the analysis of the B Sample.]~~

~~2.1.3— Excepting those substances for which a quantitative threshold is specifically identified in the Prohibited List, the presence of any quantity of a Prohibited Substance or its Metabolites or Markers in an Athlete's Sample shall constitute an anti-doping rule violation.~~

~~2.1.4 As an exception to the general rule of Article 2.1, the Prohibited List or International Standards may establish special criteria for the evaluation of Prohibited Substances that can also be produced endogenously.~~

~~2.2 Use or Attempted Use by an Athlete of a Prohibited Substance or a Prohibited Method.~~

~~[Comment to Article 2.2: It has always been the case that Use or Attempted Use of a Prohibited Substance or Prohibited Method may be established by any reliable means. As noted in the Comment to Article 3.2, unlike the proof required to establish an anti-doping rule violation under Article 2.1, Use or Attempted Use may also be established by other reliable means such as admissions by the Athlete, witness statements, documentary evidence, conclusions drawn from longitudinal profiling, including data collected as part of the Athlete Biological Passport, or other analytical information which does not otherwise satisfy all the requirements to establish "Presence" of a Prohibited Substance under Article 2.1.~~

~~For example, Use may be established based upon reliable analytical data from the analysis of an A Sample (without confirmation from an analysis of a B Sample) or from the analysis of a B Sample alone where the Anti-Doping Organization provides a satisfactory explanation for the lack of confirmation in the other Sample.]~~

~~2.2.1 It is each Athlete's personal duty to ensure that no Prohibited Substance enters his or her body and that no Prohibited Method is Used. Accordingly, it is not necessary that intent, Fault, negligence or knowing Use on the Athlete's part be demonstrated in order to establish an anti-doping rule violation for Use of a Prohibited Substance or a Prohibited Method.~~

~~2.2.2 The success or failure of the Use or Attempted Use of a Prohibited Substance or Prohibited Method is not material. It is sufficient that the Prohibited Substance or Prohibited Method was Used or Attempted to be Used for an anti-doping rule violation to be committed.~~

~~[Comment to Article 2.2.2: Demonstrating the "Attempted Use" of a Prohibited Substance or a Prohibited Method requires proof of intent on the Athlete's part. The fact that intent may be required to prove this particular anti-doping rule violation does not undermine the Strict Liability principle established for violations of Article 2.1 and violations of Article 2.2 in respect of Use of a Prohibited Substance or Prohibited Method.~~

~~An Athlete's Use of a Prohibited Substance constitutes an anti-doping rule violation unless such substance is not prohibited Out-of-Competition and the Athlete's Use takes place Out-~~

~~of Competition. (However, the presence of a Prohibited Substance or its Metabolites or Markers in a Sample collected In Competition is a violation of Article 2.1 regardless of when that substance might have been administered.)]~~

~~2.5 — Tampering or Attempted Tampering with any part of Doping Control.~~

~~Conduct which subverts the Doping Control process but which would not otherwise be included in the definition of Prohibited Methods. Tampering shall include, without limitation, intentionally interfering or attempting to interfere with a Doping Control official, providing fraudulent information to an Anti-Doping Organization or intimidating or attempting to intimidate a potential witness.~~

~~[Comment to Article 2.5: For example, this Article would prohibit altering identification numbers on a Doping Control form during Testing, breaking the B bottle at the time of B Sample analysis, or altering a Sample by the addition of a foreign substance.~~

~~Offensive conduct towards a Doping Control official or other Person involved in Doping Control which does not otherwise constitute Tampering shall be addressed in the disciplinary rules of sport organizations.]~~

- ~~Code~~ **ArticleArt. 3 — PROOF OF DOPING**

~~3.2 — Methods of Establishing Facts and Presumptions~~

~~3.2.1 Analytical methods or decision limits approved by WADA after consultation within the relevant scientific community and which have been the subject of peer review are presumed to be scientifically valid. Any Athlete or other Person seeking to rebut this presumption of scientific validity shall, as a condition precedent to any such challenge, first notify WADA of the challenge and the basis of the challenge. CAS on its own initiative may also inform WADA of any such challenge. At WADA's request, the CAS panel shall appoint an appropriate scientific expert to assist the panel in its evaluation of the challenge. Within 10 days of WADA's receipt of such notice, and WADA's receipt of the CAS file, WADA shall also have the right to intervene as a party, appear amicus curiae or otherwise provide evidence in such proceeding.~~

~~3.2.2 WADA-accredited laboratories, and other laboratories approved by WADA, are presumed to have conducted Sample analysis and custodial procedures in accordance with the International Standard for Laboratories. The Athlete or other Person may rebut this presumption by establishing that a~~

~~departure from the International Standard for Laboratories occurred which could reasonably have caused the Adverse Analytical Finding.~~

~~If the Athlete or other Person rebuts the preceding presumption by showing that a departure from the International Standard for Laboratories occurred which could reasonably have caused the Adverse Analytical Finding, then the Anti-Doping Organization shall have the burden to establish that such departure did not cause the Adverse Analytical Finding.~~

- ~~[Comment to Article 3.2.2: The burden is on the Athlete or other Person to establish, by a balance of probability, a departure from the International Standard for Laboratories that could reasonably have caused the Adverse Analytical Finding. If the Athlete or other Person does so, the burden shifts to the Anti-Doping Organization to prove to the comfortable satisfaction of the hearing panel that the departure did not cause the Adverse Analytical Finding.]~~ **Code Article Art. 4 THE PROHIBITED LIST**
- Code Art. 6 — ANALYSIS OF SAMPLES**

~~Samples shall be analyzed in accordance with the following principles:~~

~~6.1 — Use of Accredited and Approved Laboratories~~

~~For purposes of Article 2.1, Samples shall be analyzed only in WADA-accredited laboratories or laboratories otherwise approved by WADA. The choice of the WADA-accredited or WADA-approved laboratory used for the Sample analysis shall be determined exclusively by the Anti-Doping Organization responsible for results management.~~

~~[Comment to Article 6.1: For cost and geographic access reasons, WADA may approve laboratories which are not WADA-accredited to perform particular analyses, for example, analysis of blood which should be delivered from the collection site to the laboratory within a set deadline. Before approving any such laboratory, WADA will ensure it meets the high analytical and custodial standards required by WADA.]~~

~~Violations of Article 2.1 may be established only by Sample analysis performed by a WADA-accredited laboratory or another laboratory approved by WADA. Violations of other Articles may be established using analytical results from other laboratories so long as the results are reliable.]~~

~~6.2 — Purpose of Analysis of Samples~~

~~Samples shall be analyzed to detect Prohibited Substances and Prohibited Methods identified on the Prohibited List and other substances as may be directed by WADA pursuant to Article 4.5, or to assist an Anti-Doping Organization in profiling relevant~~

~~parameters in an *Athlete's* urine, blood or other matrix, including DNA or genomic profiling, or for any other legitimate anti-doping purpose. Samples may be collected and stored for future analysis.~~

~~[Comment to Article 6.2: For example, relevant profile information could be used to direct Target Testing or to support an anti-doping rule violation proceeding under Article 2.2, or both.]~~

~~6.3 — Research on Samples~~

~~No Sample may be used for research without the Athlete's written consent. Samples used for purposes other than Article 6.2 shall have any means of identification removed such that they cannot be traced back to a particular Athlete.~~

~~[Comment to Article 6.3: As is the case in most medical contexts, use of anonymized Samples for quality assurance, quality improvement, or to establish reference populations is not considered research.]~~

~~6.4 — Standards for Sample Analysis and Reporting~~

~~Laboratories shall analyze Samples and report results in conformity with the International Standard for Laboratories. To ensure effective Testing, the Technical Document referenced at Article 5.4.1 will establish risk assessment-based Sample analysis menus appropriate for particular sports and sport disciplines, and laboratories shall analyze Samples in conformity with those menus, except as follows:~~

~~6.4.1 Anti-Doping Organizations may request that laboratories analyze their Samples using more extensive menus than those described in the Technical Document.~~

~~6.4.2 Anti-Doping Organizations may request that laboratories analyze their Samples using less extensive menus than those described in the Technical Document only if they have satisfied WADA that, because of the particular circumstances of their country or sport, as set out in their test distribution plan, less extensive analysis would be appropriate.~~

~~6.4.3 As provided in the International Standard for Laboratories, laboratories at their own initiative and expense may analyze Samples for Prohibited Substances or Prohibited Methods not included on the Sample analysis menu described in the Technical Document or specified by the Testing authority. Results from any such analysis shall be reported and have the same validity and consequence as any other analytical result.~~

~~[Comment to Article 6.4: The objective of this Article is to extend the principle of "intelligent Testing" to the Sample analysis menu so as to most effectively and efficiently detect doping. It is recognized that the resources available to fight doping are limited and that increasing the Sample analysis menu may, in some sports and countries, reduce the number of Samples which can be analyzed.]~~

6.5 — Further Analysis of *Samples*

~~Any *Sample* may be subject to further analysis by the *Anti-Doping Organization* responsible for results management at any time before both the A and B *Sample* analytical results (or A *Sample* result where B *Sample* analysis has been waived or will not be performed) have been communicated by the *Anti-Doping Organization* to the *Athlete* as the asserted basis for an Article 2.1 anti-doping rule violation.~~

~~*Samples* may be stored and subjected to further analyses for the purpose of Article 6.2 at any time exclusively at the direction of the *Anti-Doping Organization* that initiated and directed *Sample* collection or WADA. (Any *Sample* storage or further analysis initiated by WADA shall be at WADA's expense.) Further analysis of *Samples* shall conform with the requirements of the International Standard for Laboratories and the International Standard for Testing and Investigations.~~

- ~~Code Article~~ Art. 10 SANCTIONS ON INDIVIDUALS

- ~~Code Art. 13~~ —APPEALS

~~13.7 — Appeals from Decisions Suspending or Revoking Laboratory Accreditation.~~

~~Decisions by WADA to suspend or revoke a laboratory's WADA accreditation may be appealed only by that laboratory with the appeal being exclusively to CAS.~~

- ~~Code Article~~ Art. 14 —CONFIDENTIALITY AND REPORTING

~~14.1 — Information Concerning Adverse Analytical Findings, Atypical Findings, and other Asserted Anti-Doping Rule Violations.~~

~~14.1.1 — Notice of Anti-Doping Rule Violations to *Athletes* and other *Persons*.~~

~~The form and manner of notice of an asserted anti-doping rule violation shall be as provided in the rules of the *Anti-Doping Organization* with results management responsibility.~~

~~14.1.2 — Notice of Anti-Doping Rule Violations to *National Anti-Doping Organizations*, International Federations, and WADA.~~

~~The *Anti-Doping Organization* with results management responsibility shall also notify the *Athlete's National Anti-Doping Organization*, International~~

~~Federation and WADA of the assertion of an anti-doping rule violation simultaneously with the notice to the *Athlete* or other *Person*.~~

~~14.1.3 Content of an Anti-Doping Rule Violation Notice.~~

~~Notification shall include: the *Athlete's* name, country, sport and discipline within the sport, the *Athlete's* competitive level, whether the test was *In-Competition* or *Out of Competition*, the date of *Sample* collection, the analytical result reported by the laboratory and other information as required by the International Standard for Testing and Investigations, or, for anti-doping rule violations other than Article 2.1, the rule violated and the basis of the asserted violation.~~

~~14.1.4 Status Reports.~~

~~Except with respect to investigations which have not resulted in notice of an anti-doping rule violation pursuant to Article 14.1.1, the *Anti-Doping Organizations* referenced in Article 14.1.2 shall be regularly updated on the status and findings of any review or proceedings conducted pursuant to Article 7, 8 or 13 and shall be provided with a prompt written reasoned explanation or decision explaining the resolution of the matter.~~

~~14.1.5 Confidentiality.~~

~~The recipient organizations shall not disclose this information beyond those *Persons* with a need to know (which would include the appropriate personnel at the applicable *National Olympic Committee*, *National Federation*, and team in a *Team Sport*) until the *Anti-Doping Organization* with results management responsibility has made *Public Disclosure* or has failed to make *Public Disclosure* as required in Article 14.3.~~

~~[Comment to Article 14.1.5: Each *Anti-Doping Organization* shall provide, in its own anti-doping rules, procedures for the protection of confidential information and for investigating and disciplining improper disclosure of confidential information by any employee or agent of the *Anti-Doping Organization*.]~~

3.0 Terms and Definitions

3.1 Code defined terms

~~**ADAMS:** The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and WADA in their anti-doping operations in conjunction with data protection legislation.~~

~~**Adverse Analytical Finding:** A report from a WADA-accredited laboratory or other WADA-approved laboratory that, consistent with the International Standard for Laboratories and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance*~~

or its *Metabolites* or *Markers* (including elevated quantities of endogenous substances) or evidence of the *Use of a Prohibited Method*.

Adverse Passport Finding: A report identified as an *Adverse Passport Finding* as described in the applicable *International Standards*.

Anti-Doping Organization: A *Signatory* that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events*, WADA, International Federations, and *National Anti-Doping Organizations*.

Athlete: Any *Person* who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each *National Anti-Doping Organization*). An *Anti-Doping Organization* has discretion to apply anti-doping rules to an *Athlete* who is neither an *International Level Athlete* nor a *National Level Athlete*, and thus to bring them within the definition of “*Athlete*.” In relation to *Athletes* who are neither *International Level* nor *National Level Athletes*, an *Anti-Doping Organization* may elect to: conduct limited *Testing* or no *Testing* at all; analyze *Samples* for less than the full menu of *Prohibited Substances*; require limited or no whereabouts information; or not require advance *TUEs*. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any *Athlete* over whom an *Anti-Doping Organization* has authority who competes below the international or national level, then the *Consequences* set forth in the *Code* (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all International and National Level Athletes are subject to the anti-doping rules of the Code, with the precise definitions of international and national level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond International or National Level Athletes to competitors at lower levels of Competition or to individuals who engage in fitness activities but do not compete at all. Thus, a National Anti-Doping Organization could, for example, elect to test recreational-level competitors but not require advance TUEs. But an anti-doping rule violation involving an Adverse Analytical Finding or Tampering results in all of the Consequences provided for in the Code (with the exception of Article 14.3.2). The decision on whether Consequences apply to recreational-level Athletes who engage in fitness activities but never compete is left to the National Anti-Doping Organization. In the same manner, a Major Event Organization holding an Event only for masters-level competitors could elect to test the competitors but not analyze Samples for the full menu of Prohibited Substances.]

Competitors at all levels of Competition should receive the benefit of anti-doping information and education.}]

Athlete Biological Passport: The program and methods of gathering and collating data as described in the

ADAMS The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and WADA in their anti-doping operations in conjunction with data protection legislation.

Adverse Analytical Finding A report from a WADA-accredited laboratory or other WADA-approved laboratory that, consistent with the *International Standard for Laboratories* and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (including elevated quantities of endogenous substances) or evidence of the *Use of a Prohibited Method*.

Adverse Passport Finding A report identified as an *Adverse Passport Finding* as described in the applicable *International Standards*.

Anti-Doping Organization A *Signatory* that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events*, WADA, International Federations, and *National Anti-Doping Organizations*.

Athlete Any *Person* who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each *National Anti-Doping Organization*). An *Anti-Doping Organization* has discretion to apply anti-doping rules to an *Athlete* who is neither an *International-Level Athlete* nor a *National-Level Athlete*, and thus to bring them within the definition of "Athlete." In relation to *Athletes* who are neither *International-Level* nor *National-Level Athletes*, an *Anti-Doping Organization* may elect to: conduct limited *Testing* or no *Testing* at all; analyze *Samples* for less than the full menu of *Prohibited Substances*; require limited or no whereabouts information; or not require advance *TUEs*. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any *Athlete* over whom an *Anti-Doping Organization* has authority who competes below the international or national level, then the *Consequences* set forth in the *Code* (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*,

government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all International- and National-Level *Athletes* are subject to the anti-doping rules of the *Code*, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and *National Anti-Doping Organizations*, respectively. The definition also allows each *National Anti-Doping Organization*, if it chooses to do so, to expand its anti-doping program beyond International- or National-Level *Athletes* to competitors at lower levels of *Competition* or to individuals who engage in fitness activities but do not compete at all. Thus, a *National Anti-Doping Organization* could, for example, elect to test recreational-level competitors but not require advance TUEs. But an anti-doping rule violation involving an *Adverse Analytical Finding* or *Tampering* results in all of the *Consequences* provided for in the *Code* (with the exception of Article 14.3.2). The decision on whether *Consequences* apply to recreational-level *Athletes* who engage in fitness activities but never compete is left to the *National Anti-Doping Organization*. In the same manner, a *Major Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not analyze *Samples* for the full menu of *Prohibited Substances*. Competitors at all levels of *Competition* should receive the benefit of anti-doping information and education.]

Athlete Biological Passport (ABP)

The program and methods of gathering and collating data as described in the International Standard for Testing and Investigations and International Standard for Laboratories.

Atypical Finding

A report from a WADA-accredited laboratory or other WADA approved laboratory, which requires further investigation as provided by the International Standard for Laboratories or related Technical Documents prior to the determination of an *Adverse Analytical Finding*.

Atypical Passport Finding

A report described as an *Atypical Passport Finding* as described in the applicable *International Standards*.

CAS

The Court of Arbitration for Sport

Code

The World Anti-Doping Code.

Competition

A single race, match, game or singular sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other sport contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.

Consequences of Anti-Doping Rule

An *Athlete's* or other *Person's* violation of an anti-doping rule may result in one or more of the following: (a) *Disqualification* means the

Violations
("Consequences")

Athlete's results in a particular Competition or Event are invalidated, with all resulting Consequences including forfeiture of any medals, points and prizes; (b) Ineligibility means the Athlete or other Person is barred on account of an anti-doping rule violation for a specified period of time from participating in any Competition or other activity or funding as provided in Article 10.12.1; (c) Provisional Suspension means the Athlete or other Person is barred temporarily from participating in any Competition or activity prior to the final decision at a hearing conducted under Article 8; (d) Financial Consequences means a financial sanction imposed for an anti-doping rule violation or to recover costs associated with an anti-doping rule violation; and (e) Public Disclosure or Public Reporting means the dissemination or distribution of information to the general public or Persons beyond those Persons entitled to earlier notification in accordance with Article 14. Teams in Team Sports may also be subject to Consequences as provided in Article 11.

Doping Control

All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, Sample collection and handling, laboratory analysis, TUEs, results management and hearings.

Event

A series of individual Competitions conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).

In-Competition

Unless provided otherwise in the rules of an International Federation or the ruling body of the Event in question, "In-Competition" means the period commencing twelve hours before a Competition in which the Athlete is scheduled to participate through the end of such Competition and the Sample collection process related to such Competition.

[Comment: An International Federation or ruling body for an Event may establish an "In-Competition" period that is different than the Event Period.]

Ineligibility

See Consequences of Anti-Doping Rule Violations above.

International
Standard

A standard adopted by WADA in support of the Code. Compliance with an International Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the International Standard were performed properly. International Standards shall include any Technical Documents issued pursuant to the International Standard.

Major Event
Organizations

The continental associations of National Olympic Committees and other international multi-sport organizations that function as the ruling body for any continental, regional or other International Event.

<u>Marker</u>	<u>A compound, group of compounds or biological variable(s) that indicates the Use of a Prohibited Substance or Prohibited Method.</u>
<u>Metabolite</u>	<u>Any substance produced by a biotransformation process.</u>
<u>National Anti-Doping Organization</u>	<u>The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of Samples, the management of test results, and the conduct of hearings at the national level. If this designation has not been made by the competent public authority(-ies), the entity shall be the country's National Olympic Committee or its designee.</u>
<u>National Olympic Committee</u>	<u>The organization recognized by the International Olympic Committee. The term National Olympic Committee shall also include the National Sport Confederation in those countries where the National Sport Confederation assumes typical National Olympic Committee responsibilities in the anti-doping area.</u>
<u>Out-of-Competition</u>	<u>Any period which is not In-Competition.</u>
<u>Person</u>	<u>A natural Person or an organization or other entity.</u>
<u>Prohibited List</u>	<u>The List identifying the Prohibited Substances and Prohibited Methods.</u>
<u>Prohibited Method</u>	<u>Any method so described on the Prohibited List.</u>
<u>Prohibited Substance</u>	<u>Any substance, or class of substances, so described on the Prohibited List.</u>
<u>Publicly Disclose or Publicly Report</u>	<u>See Consequences of Anti-Doping Rule Violations in the Code. "The dissemination or distribution of information to the general public or Persons beyond those Persons entitled to earlier notification in accordance with Article 14. Teams in Team Sports may also be subject to Consequences as provided in Article 11."</u>
<u>Sample or Specimen</u>	<u>Any biological material collected for the purposes of Doping Control.</u>
<u>Signatories</u>	<u>Those entities signing the Code and agreeing to comply with the Code, as provided in Article 23.</u>
<u>Tampering</u>	<u>Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly; obstructing, misleading or engaging in any fraudulent conduct to alter results or prevent normal procedures from occurring.</u>
<u>Target Testing</u>	<u>Selection of specific Athletes for Testing based on criteria set forth in the International Standard for Testing and Investigations.</u>

<u>Testing</u>	<u>The parts of the <i>Doping Control</i> process involving test distribution planning, <i>Sample</i> collection, <i>Sample</i> handling, and <i>Sample</i> transport to the laboratory.</u>
<u>TUE</u>	<u>Therapeutic Use Exemption, as described in Article 4.4.</u>
<u>Use</u>	<u>The utilization, application, ingestion, injection or consumption by any means whatsoever of any <i>Prohibited Substance</i> or <i>Prohibited Method</i>.</u>
<u>WADA</u>	<u>The World Anti-Doping Agency.</u>

3.2 ISL Defined Terms

<u>Adaptive Model</u>	<u>A mathematical model designed to identify unusual longitudinal results from <i>Athletes</i>. The model calculates the probability of a longitudinal profile of <i>Marker</i> values, assuming that the <i>Athlete</i> has a normal physiological condition.</u>
<u>Aliquot</u>	<u>A portion of the <i>Sample</i> of biological fluid (e.g. urine, blood) obtained from the <i>Athlete</i> used in the analytical process.</u>
<u>Analyte</u>	<u>Also known as or referred to as a substance, compound or measurand, which is analyzed and/or determined in a biological matrix using an Analytical Testing Procedure performed under controlled analytical and laboratory conditions. For anti-doping purposes, an Analyte may be a <i>Prohibited Substance</i>, a <i>Metabolite</i> of a <i>Prohibited Substance</i>, or a <i>Marker</i> of the <i>Use</i> of a <i>Prohibited Substance</i> or <i>Prohibited Method</i>.</u>
<u>Analytical Method</u>	<u>Analytical Testing Procedure, Test Method.</u>
<u>Analytical Testing</u>	<u>The parts of the <i>Doping Control</i> process performed at the Laboratory, which include <i>Sample</i> handling, analysis and reporting of results.</u>
<u>Analytical Testing Procedure</u>	<u>A Fit-for-Purpose procedure, as demonstrated through method validation, which is used to detect, identify and/or quantify Analytes in a <i>Sample</i> for <i>Doping Control</i> purposes in accordance with the ISL and relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines. An Analytical Testing Procedure is also referred to or known as an Analytical Method or Test Method.</u>
<u>Analytical Testing Restriction</u>	<u>Restriction on a Laboratory's application of specified Analytical Testing Procedure(s) or the analysis of a particular class(es) of <i>Prohibited Substances</i> or <i>Prohibited Methods</i> to <i>Samples</i>, as determined by WADA.</u>

<u>Athlete Passport Management Unit (APMU)</u>	<u>A unit composed of a <i>Person</i> or <i>Persons</i> that is responsible for the timely management of <i>Athlete Biological Passports</i> in <i>ADAMS</i> on behalf of the Passport Custodian.</u>
<u>Bias (b)</u>	<u>Deviation of a measured result from the expected or reference value when using the complete measurement procedure.</u>
<u>Certified Reference Material (CRM)</u>	<u>Reference Material (RM), characterized by a metrologically valid procedure for one or more specified properties, which is accompanied by a certificate that provides the value of the specified property and its associated uncertainty.</u>
<u>Confirmation Procedure (CP)</u>	<u>An Analytical Testing Procedure that has the purpose of confirming the presence and/or, when applicable, confirming the concentration/ratio/score and/or establishing the origin (exogenous or endogenous) of one or more specific <i>Prohibited Substances</i>, <i>Metabolite(s)</i> of a <i>Prohibited Substance</i>, or <i>Marker(s)</i> of the <i>Use of a Prohibited Substance</i> or <i>Prohibited Method</i> in a <i>Sample</i>.</u>
<u>Corrective Action Report (CAR)</u>	<u>A report describing the Root Cause Analysis investigation of a detected nonconformity and the corrective actions implemented to rectify it. If appropriate, it shall also describe the preventive actions adopted to minimize the risk of recurrence of the nonconformity.</u>
<u>Decision Limit (DL)</u>	<u>The value of the result for a Threshold Substance in a <i>Sample</i>, obtained using a validated measurement procedure, above which it can be concluded that the Threshold has been exceeded with a statistical confidence of at least 95% [see Technical Document on Decision Limits for the Confirmatory Quantification of Threshold Substances (TD DL)].</u>
<u>External Quality Assessment Scheme (EQAS)</u>	<u>Program for quality assessment of Laboratory performance, which includes the periodical distribution of urine or blood samples to Laboratories and probationary laboratories by WADA, to be analyzed for the presence or absence of <i>Prohibited Substances</i> and/or their <i>Metabolite(s)</i>, or <i>Marker(s)</i> of <i>Use of Prohibited Substances</i> or <i>Prohibited Methods</i>. The EQAS includes also the provision of blood samples to WADA-Approved Laboratories for the ABP for the analysis of the blood <i>Markers</i> of the <i>Athlete Biological Passport</i>. EQAS samples may be open (i.e. educational; in such cases the content may be indicated), blind or double-blind (in such cases the content is unknown to the Laboratories).</u>
<u>Fit(ness)-for-Purpose</u>	<u>Suitable for the intended purpose and in conformity with the ISO/IEC 17025 or ISO 15189, as applicable, the ISL and relevant Technical Document(s) and Technical Letter(s).</u>

Flexible Scope of ISO/IEC 17025 Accreditation

Status of laboratory accreditation, which allows a Laboratory or WADA-Approved Laboratory for the ABP to make and implement restricted modifications in the Scope of ISO/IEC 17025 Accreditation, as applicable, prior to the assessment by the Accreditation Body. See ISL Art. 4.4.2.2 for a detailed description of Flexible Scope of ISO/IEC 17025 Accreditation.

Further Analysis

Further Analysis means any additional Analytical Testing performed on a Sample whether using the same Analytical Method(s) or any new or additional Analytical Testing Procedure(s) (for example, new or more sensitive Analytical Methods or Analytical Methods used to identify additional Analytes).

[Prior to reporting a test result, a Laboratory may perform Further Analysis on a Sample with no approval required. After reporting a test result, Further Analysis may be performed at any time by the same Laboratory that did the original Analytical Testing or by a different Laboratory or other WADA-approved laboratory, at the direction of the Anti-Doping Organization that initiated and directed Sample collection or WADA. Any other Anti-Doping Organization that wishes to conduct Further Analysis on a stored Sample may do so with the permission of the Anti-Doping Organization that initiated and directed Sample collection or WADA and shall be responsible for any follow-up results management. Any Sample storage or Further Analysis initiated by WADA or another Anti-Doping Organization shall be at WADA's or that Organization's expense].

Identification Capability

Analytical parameter of assay technical performance. Lowest estimated concentration at which a Confirmation Procedure is capable of consistently identifying (i.e. confirming under the stated test conditions) an Analyte, for which a Reference Material is available, according to the criteria established in the Technical Document on Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for Doping Control Purposes (TD IDCR). The Identification Capability of a Laboratory cannot be higher than the MRPL; however, it may be lower. The Identification Capability is also referred to as the Limit of Identification (LOI).

Independent Witness

A Person, invited by the Testing Authority, the Laboratory or WADA to witness parts of the Analytical Testing process. The Independent Witness shall be independent of the Athlete and his/her representative(s), the Laboratory, the Sample Collection Authority, the Testing Authority / Results Management Authority or WADA, as applicable. The Independent Witness may be indemnified for his/her service.

Initial Testing Procedure (ITP)

An Analytical Testing Procedure whose purpose is to identify those Samples which may contain a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method or an elevated quantity of a Prohibited

Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

Intermediate Precision (s_w)

Variation in results observed when one or more factors, such as time, equipment, or operator are varied within a Laboratory. It is also referred to as inter-batch / inter-run precision.

International Standard for Laboratories (ISL)

The *International Standard* applicable to Laboratories and WADA-approved Laboratories for the ABP.

Laboratory Internal Chain of Custody

Documentation maintained within the Laboratory to record the chronological traceability of custody (by *Person(s)* or upon storage) and actions performed on the *Sample* and any Aliquot of the *Sample* taken for Analytical Testing.

[Laboratory Internal Chain of Custody is generally documented by a written or electronic record of the date, location, action taken, and the *Person* performing an action with a *Sample* or Aliquot.]

Laboratory(-ies)

(A) WADA-accredited laboratory(-ies) applying Test Methods and processes to provide evidentiary data for the detection and/or identification of *Prohibited Substances* or *Prohibited Methods* on the *Prohibited List* and, if applicable, quantification of a Threshold Substance in *Samples* of urine and other biological matrices in the context of *Doping Control* activities.

Laboratory Guidelines

Recommendations of Laboratory best practice provided by WADA to address specific Laboratory operations or to provide technical requirements and guidance on interpretation and reporting of results for the analysis of specific *Prohibited Substance(s)* and/or *Prohibited Method(s)* or on the application of specific Laboratory procedures.

[Laboratory Guidelines are posted on WADA's website, are not of mandatory application and may be later incorporated, partially or in full, in Technical Document(s) or in the ISL. Laboratory Guidelines are approved by the WADA Laboratory Expert Group].

Laboratory Documentation Package

The material produced by the Laboratory to support an analytical result such as an *Adverse Analytical Finding* as set forth in the WADA Technical Document for Laboratory Documentation Packages (TD LDOC).

Limit of Detection (LOD)

Analytical parameter of assay technical performance. Lowest concentration of an Analyte in a *Sample* that can be routinely detected, but not necessarily identified or quantified, under the stated test conditions.

<u>Limit of Identification (LOI)</u>	<u>Identification Capability</u>
<u>Limit of Quantification (LOQ)</u>	Analytical parameter of assay technical performance. Lowest concentration of an Analyte in a <i>Sample</i> that can be quantitatively determined with acceptable precision and accuracy (<i>i.e.</i> acceptable Measurement Uncertainty) under the stated test conditions.
<u>Major Event</u>	A series of individual international <i>Competitions</i> conducted together under an international multi-sport organization functioning as a ruling body (<i>e.g.</i> the Olympic Games, Pan American Games) and for which a significant increase of resources and capacity may be required to conduct <i>Doping Control</i> for the <i>Event</i> .
<u>Measurement Uncertainty (MU)</u>	Parameter associated with a measurement result that characterizes the dispersion of quantity values attributed to the measure and provides confidence in the validity of the measured result [see Technical Document on Decision Limits for the Confirmatory Quantification of Threshold Substances (TD DL)].
<u>Minimum Required Performance Level (MRPL)</u>	Minimum analytical criterion of Laboratory technical performance established by WADA. Minimum concentration at which a Laboratory is expected to consistently detect and confirm a <i>Prohibited Substance</i> or <i>Metabolite</i> of a <i>Prohibited Substance</i> or <i>Marker</i> of a <i>Prohibited Substance</i> or <i>Prohibited Method</i> in the routine daily operation of the Laboratory. Individual Laboratories may and are expected to achieve better performance [see Technical Document on Minimum Required Performance Levels for detection and identification of Non-Threshold Substances (TD MRPL)].
<u>Negative Finding</u>	A test result from a Laboratory which, in accordance with the effective ISL and/or relevant Technical Document(s) and/or Technical Letter(s), concludes that no <i>Prohibited Substance(s)</i> or its <i>Metabolite(s)</i> or <i>Marker(s)</i> or evidence of the <i>Use of a Prohibited Method(s)</i> , included in the requested Analytical Testing menu, were found in a <i>Sample</i> based on the applied Initial Testing Procedure(s) or Confirmation Procedure(s).
<u>Non-Threshold Substance</u>	A substance listed on the <i>Prohibited List</i> for which the identification, in compliance with the Technical Document on the Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for <i>Doping Control</i> Purposes (TD IDCR) or other applicable Technical Document(s), constitutes an <i>Adverse Analytical Finding</i> .
<u>Presumptive Adverse Analytical Finding (PAAF)</u>	The status of a <i>Sample</i> test result from the Initial Testing Procedure which represents a suspicious finding, but for which a Confirmation

	<u>Procedure to render a conclusive test result has not yet been performed.</u>
<u>Provisional Suspension</u>	<u>Temporary Suspension of a Laboratory's WADA accreditation pending a final decision by WADA regarding its accreditation status.</u>
<u>Reference Collection (RC)</u>	<u>A collection of samples or isolates of known origin that may be used in the determination of the identity of an unknown substance. For example, a well-characterized sample obtained from a controlled administration or from <i>in vitro</i> studies in which the presence of the substance of interest has been established.</u>
<u>Reference Material (RM)</u>	<u>Reference Substance or Reference Standard, which is sufficiently characterized, homogeneous and stable with respect to one or more specified properties and that has been established to be fit for its intended use in an Analytical Testing Procedure.</u>
<u>Repeatability (s_r)</u>	<u>Variability of results obtained within a laboratory using the same method, over a short time, using a single operator, item of equipment, etc. It is also referred to as intra-batch / intra-run precision.</u>
<u>Reproducibility (s_R)</u>	<u>Variability of results obtained when different laboratories analyze Aliquots of the same sample. Reproducibility is a property of the results obtained and represents a measurable agreement of analytical results between different laboratories.</u>
<u>Revocation</u>	<u>The permanent withdrawal of a Laboratory's WADA accreditation.</u>
<u>Root Cause Analysis (RCA)</u>	<u>An investigation to identify one or more fundamental cause(s) of a nonconformity based on the collection of objective evidence from an assessment of the likely factors that led to the nonconformity. The removal of a root cause factor prevents the recurrence of the nonconformity; in contrast, removing a causal factor can improve the outcome, but it does not prevent the recurrence of the problem with certainty.</u>
<u>Selectivity</u>	<u>The ability of the Analytical Testing Procedure to detect only the substance of interest, without interferences from the matrix or from other substance(s) present in the <i>Sample</i>.</u>
<u>Suspension</u>	<u>The temporary withdrawal of a Laboratory's WADA accreditation.</u>
<u>Technical Document</u>	<u>Technical requirements produced by WADA on specific anti-doping topics. Technical Documents supersede any previous publication on a similar topic, or, if applicable, the ISL.</u> <u>[Implementation of the requirements described in a Technical Document is mandatory. Technical Documents are approved by the WADA Executive Committee and posted on WADA's website. All Laboratories and WADA-</u>

Approved Laboratory for the ABP shall have the requirements of a Technical Document implemented in their procedures no later than its "effective date"].

Technical Letter Mandatory technical requirements provided by WADA in letter format from time to time (*ad-hoc*) to address particular issues on the analysis, interpretation and reporting of specific *Prohibited Substance(s)* and/or *Prohibited Method(s)* or on the application of specific Laboratory or WADA-Approved Laboratory for the ABP procedures.

[Technical Letters are approved by the WADA Executive Committee, and become effective immediately, unless otherwise specified by WADA].

Technical Note Technical guidance provided by WADA to Laboratories on the performance of specific Laboratory methods or procedures.

[Technical Notes are not considered part of Technical Documents and therefore are not of mandatory application. Technical Notes are approved by the WADA Laboratory Expert Group and become effective immediately].

Test Method Analytical Testing Procedure, Analytical Method.

Threshold The maximum permissible level of the concentration, ratio or score for a Threshold Substance in a *Sample*. The Threshold is used to establish the Decision Limit for reporting an *Adverse Analytical Finding* or *Atypical Finding* for a Threshold Substance.

Threshold Substance An exogenous or endogenous *Prohibited Substance, Metabolite* or *Marker* of a *Prohibited Substance* for which the identification and quantitative determination (e.g. concentration, ratio, score) in excess of a pre-determined Decision Limit, or, when applicable, the establishment of an exogenous origin, constitutes an *Adverse Analytical Finding*. Threshold Substances are identified as such in the Technical Document on Decision Limits (TD DL).

WADA-Approved Laboratory(-ies) for the ABP Laboratory(-ies), not otherwise accredited by WADA, which apply Analytical Methods and processes in support of the hematological module of the ABP program and in accordance with the criteria for approval of non-accredited laboratories for the ABP.

3.3 International Standard for Testing and Investigations ~~and International Standard for Laboratories.~~

~~**Atypical Finding:** A report from a WADA-accredited laboratory or other WADA-approved laboratory which requires further investigation as provided by the International Standard for Laboratories or related Technical Documents prior to the determination of an *Adverse Analytical Finding*.~~

~~**Atypical Passport Finding:** A report described as an *Atypical Passport Finding* as described in the applicable *International Standards*.~~

~~**CAS:** The Court of Arbitration for Sport.~~

~~**Code:** The World Anti-Doping Code.~~

~~**Competition:** A single race, match, game or singular sport contest. For example, a basketball game or the finals of the Olympic 100 meter race in athletics. For stage races and other sport contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.~~

~~**Doping Control:** All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, *TUEs*, results management and hearings.~~

~~**Event:** A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).~~

~~**In-Competition:** Unless provided otherwise in the rules of an International Federation or the ruling body of the *Event* in question, "*In-Competition*" means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.~~

~~[Comment: An International Federation or ruling body for an *Event* may establish an "*In-Competition*" period that is different than the *Event Period*.]~~

~~**International Standard:** A standard adopted by WADA in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standards* shall include any Technical Documents issued pursuant to the *International Standard*.~~

~~**Major Event Organizations:** The continental associations of *National Olympic Committees* and other international multi-sport organizations that function as the ruling body for any continental, regional or other *International Event*.~~

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

~~**Metabolite:** Any substance produced by a biotransformation process.~~

~~**National Anti-Doping Organization:** The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Samples*, the management of test results, and the conduct of hearings at the national level. If this designation has not been made by the competent~~

public authority(ies); the entity shall be the country's *National Olympic Committee* or its designee.

National Olympic Committee: The organization recognized by the International Olympic Committee. The term *National Olympic Committee* shall also include the National Sport Confederation in those countries where the National Sport Confederation assumes typical *National Olympic Committee* responsibilities in the anti-doping area.

Out-of-Competition: Any period which is not *In-Competition*.

Person: A natural *Person* or an organization or other entity.

Prohibited List: The List identifying the *Prohibited Substances* and *Prohibited Methods*.

Prohibited Method: Any method so described on the *Prohibited List*.

Prohibited Substance: Any substance, or class of substances, so described on the *Prohibited List*.

Publicly Disclose or Publicly Report: See *Consequences of Anti-Doping Rule Violations in the Code*. "The dissemination or distribution of information to the general public or Persons beyond those Persons entitled to earlier notification in accordance with Article 14. Teams in Team Sports may also be subject to *Consequences* as provided in Article 11."

Sample or Specimen: Any biological material collected for the purposes of *Doping Control*.

[Comment: It has sometimes been claimed that the collection of blood Samples violates the tenets of certain religious or cultural groups. It has been determined that there is no basis for any such claim.]

Signatories: Those entities signing the *Code* and agreeing to comply with the *Code*, as provided in Article 23.

Tampering: Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly; obstructing, misleading or engaging in any fraudulent conduct to alter results or prevent normal procedures from occurring.

Target Testing: Selection of specific *Athletes* for *Testing* based on criteria set forth in the International Standard for Testing and Investigations.

Testing: The parts of the *Doping Control* process involving test distribution planning, Sample collection, Sample handling, and Sample transport to the laboratory.

TUE: Therapeutic Use Exemption, as described in Article 4.4.

Use: The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method*.

WADA: The World Anti-Doping Agency.

~~[Comment: Defined terms shall include their plural and possessive forms, as well as those terms used as other parts of speech.]~~

1.1 — ISL and related Technical Documents defined Terms

Adaptive Model: A mathematical model that was designed to identify unusual longitudinal results from *Athletes*. The model calculates the probability of a longitudinal profile of *Marker* values assuming, that the *Athlete* has a normal physiological condition.

Aliquot: A portion of the *Sample* of biological fluid or tissue (e.g. urine, blood) obtained from the *Athlete* used in the analytical process.

Analytical Testing: The parts of the *Doping Control* process involving *Sample* handling, analysis and reporting following receipt in the *Laboratory*.

Athlete Passport Management Unit (APMU): A unit composed of a *Person* or *Persons*, designated by the *Anti Doping Organization*, responsible for the administrative management of the *Passports* advising the *Anti Doping Organization* for intelligent, *Targeted Testing* liaising with the *Expert Panel* compiling and authorizing an *Athlete Biological Passport Documentation Package* and reporting *Adverse Passport Findings*.

Certified Reference Material: *Reference Material*, characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty and a statement of metrological traceability.

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence or to measure the concentration/ratio of one or more specific *Prohibited Substances*, *Metabolite(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use of a Prohibited Substance* or *Method* in a *Sample*.

*[Comment: A Confirmation Procedure for a threshold substance shall also indicate a concentration/ratio of the *Prohibited Substance* greater than the applicable Decision Limit (as noted in the TD-DL).]*

Decision Limit: a concentration, accounting for the maximum permitted combined uncertainty, above which an *Adverse Analytical Finding* shall be reported.

Fit(ness) for purpose: suitable for the intended purpose and compliant to the ISO/IEC 17025 or 15189, ISL and applicable technical documents.

Flexible Scope of Accreditation: Process for a *Laboratory* to make and implement restricted modifications in the scope of the accreditation prior to the assessment by the national accreditation body. Please see section 4.4.12 for a detailed description of Flexible Scope of Accreditation.

Further Analysis: Any analysis for any substance or method except where an *Athlete* has previously been notified of an asserted anti-doping rule violation based on an *Adverse Analytical Finding* for that substance or method.

~~Initial Testing Procedure: An analytical test procedure whose purpose is to identify those Samples which may contain a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method or the quantity of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.~~

~~Intermediate Precision: Variation in results observed when one or more factors, such as time, equipment, or operator are varied within a Laboratory.~~

~~International Standard for Laboratories (ISL): The International Standard applicable to Laboratories as set forth herein.~~

~~Laboratory Internal Chain of Custody: Documentation of the sequence of Persons in custody of the Sample and any Aliquot of the Sample taken for Analytical Testing.~~

~~[Comment: Laboratory Internal Chain of Custody is generally documented by a written record of the date, location, action taken, and the individual performing an action with a Sample or Aliquot.]~~

~~Laboratory(ies): (A) WADA-accredited laboratory(ies) applying test methods and processes to provide evidentiary data for the detection of Prohibited Substances, Methods or Markers on the Prohibited List and, if applicable, quantification of a Threshold Substance in Samples of urine and other biological matrices in the context of anti-doping activities.~~

~~Laboratory Documentation Packages: The material produced by the Laboratory to support an analytical result such as an Adverse Analytical Finding as set forth in the WADA Technical Document for Laboratory Documentation Packages.~~

~~Major Event: A series of individual international Competitions conducted together under an international multi-sport organization functioning as a ruling body (e.g., the Olympic Games, Pan American Games) and for which a significant increase of resources and capacity, as determined by WADA, is required to conduct Doping Control for the Event.~~

~~Measurement Uncertainty (MU): Parameter associated with a measurement result that characterizes the dispersion of quantity values attributed to a measurand. [Comment: Knowledge of the MU increases the confidence in the validity of a measurement result.]~~

~~Minimum Required Performance Level (MRPL): concentration of a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Method that a doping Laboratory is expected to reliably detect and confirm in the routine daily operation of the Laboratory. See Technical Document Minimum Required Performance Levels for detection of Prohibited Substances.~~

~~Non-Threshold Substance: A substance listed on the Prohibited List for which the identification, in compliance with the Technical Document on the Identification Criteria for Qualitative Assays (TD-IDCR), constitutes an Adverse Analytical Finding.~~

~~**Presumptive Adverse Analytical Finding:** The status of a *Sample* test result for which there is a suspicious result in the *Initial Testing Procedure*, but for which a confirmation test has not yet been performed.~~

~~**Reference Collection:** A collection of samples of known origin that may be used in the determination of the identity of an unknown substance. For example, a well characterized sample obtained from a controlled administration study in which scientific documentation of the identity of *Metabolite(s)* can be demonstrated.~~

~~**Reference Material:** Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.~~

~~**Repeatability, s_r :** Variability observed within a *Laboratory*, over a short time, using a single operator, item of equipment, etc.~~

~~**Reproducibility, s_R :** Variability obtained when different *Laboratories* analyze the same *Sample*.~~

~~**Revocation:** The permanent withdrawal of a *Laboratory's* WADA accreditation.~~

~~**Suspension:** The temporary withdrawal of a *Laboratory's* WADA accreditation.~~

~~**Threshold Substance:** An exogenous or endogenous *Prohibited Substance*, *Metabolite* or *Marker* of a *Prohibited Substance* which is analyzed quantitatively and for which an analytical result (concentration, ratio or score) in excess of a pre-determined *Decision Limit* constitutes an *Adverse Analytical Finding*. *Threshold Substances* are identified as such in the Technical Document on *Decision Limits* (TD-DL).~~

~~**WADA-Approved Laboratory for the ABP:** *Laboratory(ies)* not otherwise accredited by WADA; applying test methods and processes in support of an *Athlete Biological Passport* program and in accordance with the criteria for approval of non-accredited laboratories for the *Athlete Biological Passport*.~~

International Standard for Testing and Investigations (ISTI) Defined Terms

~~**Results Management Authority:** The organization that is responsible, in accordance with *Code* Article 7.1, for the management of the results of *Testing* (or other evidence of a potential anti-doping rule violation) and hearings, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, WADA, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization acting pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation). In respect of *Whereabouts Failures*, the *Results Management Authority* shall be as set out in Article I.5.1.~~

~~*Sample Collection Authority:* The organisation that is responsible for the collection of *Samples* in compliance with the requirements of the International Standard for Testing and Investigations, whether (1) the *Testing Authority* itself; or (2) another organization (for example, a third party contractor) to whom the *Testing Authority* has delegated or sub-contracted such responsibility (provided that the *Testing Authority* always remains ultimately responsible under the *Code* for compliance with the requirements of the International Standard for Testing and Investigations relating to collection of *Samples*).~~

~~*Test Distribution Plan:* A document written by an *Anti-Doping Organization* that plans *Testing* on *Athletes* over whom it has *Testing Authority*, in accordance with the requirements of Article 4 of the International Standard for Testing and Investigations.~~

~~*Testing Authority:* The organization that has authorized a particular *Sample* collection, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, WADA, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization conducting *Testing* pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation).~~

~~2.0~~

~~3.0~~

Results
Management
Authority

The organization that is responsible, in accordance with *Code* Art. 7.1, for the management of the results of *Testing* (or other evidence of a potential anti-doping rule violation) and hearings, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, WADA, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization acting pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation). In respect of Whereabouts Failures, the Results Management Authority shall be as set out in Art. I.5.1.

Sample Collection
Authority

The organization that is responsible for the collection of *Samples* in compliance with the requirements of the International Standard for Testing and Investigations, whether (1) the Testing Authority itself; or (2) another organization (for example, a third party contractor) to whom the Testing Authority has delegated or subcontracted such responsibility (provided that the Testing Authority always remains ultimately responsible under the *Code* for compliance with the requirements of the International Standard for Testing and Investigations relating to collection of *Samples*).

Sample Collection
Session

All of the sequential activities that directly involve the *Athlete* from the point that initial contact is made until the *Athlete* leaves the Doping Control Station after having provided his/her *Sample(s)*.

Suitable Volume of
Urine for Analysis

A minimum of 90 mL, whether the Laboratory will be analyzing the *Sample* for all or only some *Prohibited Substances* or *Prohibited Methods*.

Test Distribution
Plan

A document written by an *Anti-Doping Organization* that plans *Testing* on *Athletes* over whom it has Testing Authority, in accordance with the requirements of Art. 4 of the International Standard for Testing and Investigations.

Testing Authority

The organization that has authorized a particular *Sample* collection, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, WADA, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization conducting *Testing* pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation).

PART TWO: —LABORATORY ACCREDITATION REQUIREMENTS AND OPERATING STANDARDS

4.0 Process and Requirements for WADA Laboratory Accreditation

This section describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining WADA accreditation, including requirements for Major Events.

4.1 ~~Applying for a WADA Applicant~~ Laboratory Accreditation

In principle, any laboratory that satisfies the criteria listed below may apply to become a candidate laboratory for WADA accreditation. However, the WADA Executive Committee, in its sole discretion, may accept or deny a laboratory's candidacy application based on the identified needs (or lack thereof) for anti-doping Analytical Testing on a regional or national scale, or for any other reason(s).

4.1.1 Expression of ~~interest~~Interest

The ~~candidate applicant~~ laboratory shall officially contact WADA in writing to express its interest in ~~the becoming a WADA accreditation process accredited laboratory.~~

~~4.1.1—Submitting initial application form~~

~~4.1.2 The candidate laboratory shall complete the necessary information in the Submit Initial~~ Application Form ~~as~~

The applicant laboratory shall submit the completed Application Form, provided by WADA and deliver this to WADA. The Application shall be duly signed by the Laboratory laboratory Director and, if relevant, by the Director of the host organization- (e.g. university, hospital, public institution).

At this stage, WADA will verify theAn applicant laboratory may only submit an application if its host country satisfies the following conditions:

- The existence of a National Anti-Doping Program ~~conducted by a National Anti-Doping Organization and/or a Regional Anti-Doping Organization, which is~~ compliant with the Code and the International Standards) in the country where of the candidate laboratory is located, theWorld Anti-Doping Program;
- The ratification of the UNESCO Convention against Doping in Sport ~~by the host country of the candidate laboratory, as well as the- and~~
- The payment of the ~~nation's annual~~ financial contributions to WADA.

4.1.1.2—Providing letter(s) of support

~~Upon successful completion~~ These conditions shall be documented as part of the application.

4.1.1.3 Provision ~~of the above, the candidate laboratory shall be requested by WADA to provide an official letter~~ Letters of support from Signatory Anti-Doping Organization(s). Such letter(s) of support will guarantee that annually a minimum of 3000 Samples from Code-compliant clients (as determined by WADA) will be provided to the laboratory for a three (3) year period within two (2) years of obtaining accreditation. The candidate laboratory shall submit a business plan which is accompanied with Support

Upon receipt of an application and verification of the conditions mentioned above, WADA shall request that the applicant laboratory submit the following letters of support:

Official letter(s) of support from host entities acceptable to WADA (e.g. universities, hospitals, private organization/organizations and/or public authorities/institutions) that:

- ~~Guarantee~~ guarantee sufficient annual financial support for a minimum of three (3) years;
- ~~Guarantee, the necessary provision of adequate~~ analytical facilities and instrumentation;
- Support for and human resources, as well as support for training programs, research and development activities;

4.1.1.3—Description of the candidate laboratory

- ~~The Official letter(s) of support from Signatory, Code-compliant (as determined by WADA) Anti-Doping Organizations such as a National Anti-Doping Organization or Regional Anti-Doping Organization responsible for a National Anti-Doping Program, or an International Federation responsible for an International Anti-Doping Program. Such letter(s) of support shall indicate a commitment to provide the Laboratory with a minimum of 3,000 Samples⁶ per year within two (2) years of obtaining WADA accreditation;~~
- A declaration by the supporting Anti-Doping Organization(s) that their relationship with the applicant laboratory is compliant with ISL Art. 4.2.3.

⁶ To determine the minimum number of Samples, each urine Sample, blood Sample and ABP blood Sample provided to the Laboratory shall count as an individual Sample.

4.1.4 Provision of Business Plan

WADA shall request the applicant laboratory to submit a business plan, which shall include market considerations (clients, number of Samples, maintenance costs, etc.), facility, instrumental, staffing and training needs, and shall guarantee the long-term provision of adequate financial and human resources to the laboratory.

4.2 Candidate Laboratory

The application materials described in ISL Arts. 4.1.1 to 4.1.4 shall be evaluated by the WADA Executive Committee to determine whether the applicant laboratory will be granted WADA candidate laboratory status and thereby continue within the WADA accreditation process. Additional supporting documentation may be requested by, and at the discretion of, the WADA Executive Committee.

4.2.1 Description of the Candidate Laboratory

Once approved by the WADA Executive Committee, the candidate laboratory shall ~~then~~ complete a detailed questionnaire provided by WADA and submit it to WADA ~~no later than~~ within eight (8) weeks following ~~the receipt of the questionnaire~~. The questionnaire will include, but is not limited to, the following:

- ~~Staff list and their qualifications, including description of any relevant anti-doping experience and a list of relevant scientific publications by laboratory staff;~~
- ~~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.~~
 - ~~Physical Security: specific measures to maintain a secure laboratory environment (e.g., CCTV monitoring, restricted access to sample storage areas);~~
 - ~~IT Security: implementation of firewalls and other cyber security measures consistent with best practice and any applicable governmental regulations (see ISL Arts. 5.2.3.4.1 and 5.2.3.4.2);~~
 - ~~Information Technology (IT) infrastructure: implementation of a data and information management system (e.g. LIMS), central server/intranet which allows secure data handling (see ISL Arts. 5.2.3.4.3 and 5.2.3.4.4).~~
- ~~List of actual and proposed and actual instrumental resources and equipment, including year of purchase and conditions for instrument technical support (access to manufacturer maintenance services);~~
- ~~Method validation data;~~
- ~~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 Measurement Uncertainties (MU):

- Status of method development and validation, including, at minimum, all mandatory Analytical Methods and method validation reports (if completed):

- List of available **Reference Materials** and/or standards **Reference Collections**, or plans to acquire **Reference Materials** and/or standards, including properly validated biological **Sample** or obtain **Reference Collections**:

- ~~Business plan for the laboratory demonstrating commitment to analyse 3000 **Samples** from **Code**-compliant **Testing Authorities** (as determined by **WADA**) annually, within two (2) years of receiving accreditation;~~

- List of **laboratory** sponsors of the laboratory;

- Contract or Memorandum of Understanding with a WADA-accredited Laboratory, which will provide mentoring and training for at least the period spanning the probationary phase of accreditation;

- Status of ISO/IEC 17025 accreditation;

- Description of customs regulations in the host country with respect to the reception of urine and blood samples, **Reference Materials** and consumables from abroad and the ability to ship **Samples** outside the country as needed; and

- Letter of compliance with the Code of Ethics (ISL Annex A) signed by the laboratory Director.

WADA may require an update of this documentation during the process of accreditation.

1.1.4—Conducting initial visit

~~WADA usually conducts an initial visit (2-3 days) to the candidate laboratory at the candidate laboratory's expense. The purpose of this visit is to clarify issues with regard to the accreditation process and the defined requirements in the ISL and to obtain information about different aspects of the laboratory relevant for the accreditation. Such a visit could be conducted prior to or during the accreditation process.~~

1.1.5—Issuing final report and recommendation

~~Within approximately twelve (12) weeks after the initial visit or the receipt of the questionnaire, WADA will complete and submit a report to the candidate laboratory. In the report WADA will make the necessary recommendations with respect to granting the candidate laboratory the status of WADA probationary laboratory or, if this is not the case, identify needed improvements in order to be considered a WADA probationary laboratory.~~

4.1.2.4.2.2 Payment of Initial accreditation fee **Accreditation Fee**

Prior to entering the probationary period, the candidate laboratory shall pay ~~to~~ WADA a one-time non-refundable fee to cover the costs related to the ~~laboratory~~ initial accreditation process. This fee shall be

determined by WADA.

4.1.34.2.3 Laboratory independence/Independence and Impartiality

~~The Laboratory~~ In order to avoid potential conflicts of interest, the laboratory shall be established administratively and remain operationally independent from any organization, which could exert undue pressure on the laboratory and affect the impartial execution of its tasks and operations. This applies to, but is not limited to, *Anti-Doping Organizations* ~~to or any other sport or political organizations.~~ This is necessary in order to ensure full confidence in ~~its~~ the laboratory's competence, impartiality, judgment or operational integrity, in compliance with ~~section 4.1.5d of~~ ISO/IEC 17025. ~~Operational~~

- ~~Administrative independence implies~~ requires that the ~~Laboratory shall have~~ laboratory is a separate budget permitting the ~~Laboratory to~~ legal entity without any administrative links to an *Anti-Doping Organization* or other sport or political organizations;
- ~~Operational independence requires that the laboratory shall manage its own affairs without hindrance or, interference, or direction from any Anti-Doping Organization, sport organizations or any Person.~~ This requires the laboratory to have a dedicated budget allowing the implementation of an efficient approval process for the timely procurement of necessary Reference Materials, reagents, consumables and essential equipment, as well as independent laboratory management decisions concerning the recruitment, retention and training of staff, participation in scientific meetings and symposia, etc. This does not prevent the laboratory from receiving research grants or other financial support from their host organization (e.g. university, hospital, public institution), *Anti-Doping Organizations*, sport organizations, government, or other sponsors, and following applicable accounting regulations in connection with the receipt and management of those funds.

4.1.44.2.4 Compliance with the Code of Ethics (ISL Annex A)

The candidate laboratory shall implement and comply with the provision(s) ~~in of~~ the Code of Ethics ~~(Annex B) which are relevant for a laboratory in the probationary period.~~ The laboratory shall ~~communicate~~ provide the Code of Ethics to all employees and ensure ~~their~~ understanding ~~of~~ and commitment ~~to the different~~ compliance with all aspects of the Code of Ethics. ~~The candidate laboratory shall provide to WADA a letter of compliance with the Code of Ethics, signed by the Laboratory Director.~~

1.2 Preparing for WADA Laboratory Accreditation

4.2.5 Pre-Probationary Test and On-Site Assessment

Prior to entering the probationary period, ~~the candidate laboratory may be required to participate in~~ WADA shall conduct a pre-probationary test, consisting of at least ten EQAS samples in order to assess its competence at that time. The pre-probationary test may be conducted in conjunction with an initial site visit as described in 4.1.5. The candidate laboratory shall ~~successfully identify and document concentrations in excess of the threshold(s) or~~ Minimum

~~Required Performance Levels (MRPL), as applicable, of the Prohibited Substances, Metabolite(s) of Prohibited Substances, or Marker(s) of Prohibited Substances or Prohibited Methods within a time frame of ten to 15 working days as determined by WADA. The candidate laboratory shall provide a test report for each of the samples in the pre-probationary test. For negative samples, WADA may request all or a portion of the negative Initial Testing Procedure data. For selected (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 with regard to the accreditation process, which are relevant for the WADA accreditation.~~

4.2.5.1 As part of the PPT, the candidate laboratory shall be required to analyze at least ten (10) blind EQAS samples. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in ISL Sections 6 and 7, respectively.

4.2.5.2 The candidate laboratory shall report the results for the PPT blind EQAS samples in ADAMS (in compliance with ISL Art. 6.4) within a period of fifteen (15) working days, unless otherwise notified by WADA.

- Upon request, the candidate laboratory shall provide WADA with a Laboratory Documentation Package for selected EQAS samples for which there is an Adverse Analytical Finding; the candidate laboratory shall provide a Laboratory Documentation Package. Additional data to may be provided required upon WADA's request. The candidate laboratory's This documentation shall be submitted within ten (10) working days of WADA's request or as otherwise indicated by WADA;
- For selected EQAS samples with Negative Findings, WADA may request all or a portion of the Initial Testing Procedure data.

4.2.5.3 After receiving the PPT EQAS results, WADA shall inform the candidate laboratory of the evaluation of its performance in the pre-probationary test shall be taken into consideration by WADA to gauge the laboratory's competence as well as allow WADA to provide feedback on areas in need of and provide guidance for improvement. Corrective actions, if any, shall be conducted and reported by the laboratory upon request. Such testing candidate laboratory to WADA within thirty (30) calendar days, or as otherwise indicated by WADA.

4.2.5.4 In addition, WADA shall provide an Assessment Report regarding the outcomes of the on-site assessment, including any identified nonconformity(-ies), in order to allow the candidate laboratory to implement the necessary improvements. Corrective actions, if requested by WADA, shall be conducted and reported by the candidate laboratory to WADA within thirty (30) calendar days, or as otherwise indicated by WADA.

The nonconformities identified in the WADA Assessment Report shall be satisfactorily addressed and the recommendations for improvement should be implemented before the candidate laboratory can be accepted as a WADA probationary laboratory. The candidate laboratory's performance in the PPT and on-site assessment will be taken into account 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.

4.2.5.5 The maximum length of time during which a laboratory can remain as a candidate laboratory is three (3) years, unless WADA determines that there are exceptional circumstances that justify an extension of this period.

4.1.4.14.2.5.6 Upon successful/satisfactory completion of the provisions of section 4.1 and following official notification/candidate laboratory requirements (as per ISL Art. 4.2), as determined by WADA/the LabEG, a candidate laboratory enters the probationary phase of WADA accreditation under the title of/as a "WADA probationary laboratory". The probationary period shall incorporate at least 20 EQAS samples, typically distributed over multiple EQAS rounds, in order to prepare the probationary laboratory for the initial accreditation. During this period, WADA shall provide appropriate feedback to assist the laboratory in improving the quality of its testing process. In this period the laboratory shall successfully complete provisions 4.2.1 to 4.2.5.

4.3 Probationary Laboratory

4.1.54.3.1 Obtaining -ISO/IEC 17025 accreditation/Accreditation by the laboratory/Laboratory

The probationary laboratory shall be accredited by a relevant accreditation body to obtain ISO/IEC 17025 accreditation from an Accreditation Body, with primary reference to the interpretations/interpretation and applications/application of the ISO/IEC 17025 requirements as described in the Application of ISO/IEC 17025 to the Analysis of Urine Doping Control/to the analysis of Samples (see ISL Section 5.0) and the Application of ISO/IEC 17025 to the Analysis of Blood Doping Control Samples (Section 6.0). The relevant accreditation body). 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).

The probationary laboratory shall prepare and establish the required documentation and procedures/Management System according to the requirements in Application of ISO/IEC 17025 applicable to the Analysis/analysis of Urine Doping Control Samples (see ISL Section 5.0) and the Application of ISO/IEC 17025 to the Analysis of Blood Doping Control Samples (Section 6.0), as applicable. Based on this, the laboratory shall initiate and prepare for the accreditation process by consulting with a relevant accreditation body. An assessment by the representative(s) of a relevant accreditation body, including an ISL-trained assessor, shall be conducted/Accreditation Body. The probationary laboratory shall correct and document any identified non-conformities/nonconformities with the ISO/IEC 17025 standard within the defined time frames and document this accordingly./timelines.

Summaries/The Accreditation Body should send a summary of the Assessment Report and any corrective/preventive action documentation of correction of non-conformities/addressing

nonconformities, in English or French, ~~should be sent to WADA by the relevant accreditation body.~~ Should the probationary laboratory prefer to send the information directly to WADA, the laboratory shall do so within a reasonable ~~time frame~~timeline.

The ISO/IEC 17025 accreditation shall be obtained before the end of the probationary period. This is a critical and mandatory pre-requisite for obtaining WADA accreditation.

4.1.64.3.2 Participating in the WADA External Quality Assessment Scheme EQAS Program

During the probationary period, the laboratory shall successfully analyze at least ~~(10)~~fifteen (15) blind EQAS samples in, distributed over multiple EQAS rounds (See Annex A within a period of twelve (12) months (see ISL Section 6 for a description of the EQAS).

~~After successful completion of During this period, WADA shall provide feedback to assist the probationary period, as a final proficiency test, the laboratory shall analyze a minimum to improve the quality of (20) EQAS samples in the presence of WADA representatives. The final accreditation test shall assess both the scientific competence and the capability of the laboratory to manage multiple Samples. The probationary laboratory shall successfully identify and/or document a concentration in excess of the threshold or Minimum Required Performance Level (MRPL) of the Prohibited Substances, Metabolite(s) of Prohibited Substances, or Marker(s) of Prohibited Substances or Prohibited Methods within five calendar days of opening the samples. The probationary laboratory shall provide a Test Report for each of the samples in the proficiency test. For negative samples, WADA may request all or a portion of the negative Initial Testing Procedure data. For selected samples for which there is an Adverse Analytical Finding, the probationary laboratory shall provide a Laboratory Documentation Package. This documentation shall be submitted within two (2) weeks of WADA's request. Costs associated with the WADA on-site visit shall be at the laboratory's expense its Analytical Testing process.~~

The probationary laboratory shall successfully report the results for the blind EQAS samples to WADA in accordance with ISL Art. 6.4 within a period determined by WADA. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in ISL Sections 6 and 7, respectively.

4.1.74.3.3 Planning and implementing research and development activitiesImplementing Research and Development Activities

The probationary laboratory shall develop a plan for its research and development activities in the field of ~~Doping Control within anti-doping science, for the initial three (3)-year period including a budget. The probationary laboratory shall demonstrate in its budget an allocation to research and development activities in the field of Doping Control of after obtaining WADA~~

accreditation, allocating at least 7% of the operational annual budget ~~for the initial three-year period expected from activities associated with Code-compliant Anti-Doping Organizations.~~

At least two (2) research and development activities shall be initiated and implemented within the probationary period ⁷. The research activities can either be conducted by the probationary laboratory alone or in cooperation with other ~~WADA-accredited Laboratories~~ or other research organizations.

As part of its laboratory monitoring activities, WADA may request documented evidence of the research and development activities in the field of anti-doping science implemented by the probationary laboratory.

4.1.84.3.4 Planning and implementing sharing of knowledge

~~The~~During the probationary period, the probationary laboratory shall demonstrate ~~during the probationary period~~ its willingness and ability to collaborate and share knowledge with other ~~WADA-accredited Laboratories~~. ~~The probationary laboratory shall prepare and convey information and knowledge on at least two specific issues to the other WADA-accredited Laboratories within the probationary period.~~ A description of this sharing of knowledge is provided in the Code of Ethics (ISL Annex BA).

4.1.94.3.5 Professional ~~liability insurance coverage~~ Liability Insurance Coverage

~~Probationary~~Before WADA grants accreditation, probationary laboratories shall provide documentation to WADA that professional liability risk insurance coverage has been obtained to cover liability ~~to an amount~~ of no less than two (2) million USD annually.

4.4 WADA-Accredited Laboratory

4.1.104.4.1 Obtaining WADA accreditation

1.2.1 Participating in a WADA accreditation audit

4.4.1.1 In the last phase of WADA Accreditation Assessment

4.4.1.1.1 Once WADA has determined that the laboratory has successfully completed the requirements of the probationary period ~~WADA will prepare in cooperation with the laboratory a final WADA accreditation, and upon request by the probationary laboratory stating its readiness to proceed further, a Final Accreditation Test (FAT) and on-site assessment— shall be conducted by WADA.~~

⁷ 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.

Representative(s) of the Accreditation Body may be invited as observers to the WADA on-site assessment.

4.4.1.1.2 As part of the FAT, the probationary laboratory shall analyze a minimum of fifteen (15) blind EQAS samples in the presence of a WADA assessment team. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in ISL Sections 6 and 7, respectively.

4.4.1.1.3 Compliance with the defined requirements in the Application of ISO/IEC 17025 to the Analysisanalysis of Urine Doping Control Samples (Section 5.0) and, if necessary, the Application of ISO/IEC 17025 to the Analysis of Blood Doping Control Samples (Section 6.0), the ISL and other WADA Laboratory standards (Technical Documents, Technical Letters, Laboratory Guidelines), and the practice and documentation of the laboratory will be assessed. If WADA has participated in the initial ISO/IEC 17025 assessment, The FAT shall assess both the scientific competence and the final WADA assessment may only consistcapability of a document audit. Otherwise, the audit can be conducted together with the relevant accreditation body or separately if more practical. Should an on-site audit take place by WADA, theprobationary laboratory to manage multiple Samples.

4.4.1.1.4 Costs associated eostwith the WADA on-site visit and FAT shall be at the probationary laboratory's expense.

4.4.1.1.5 The probationary laboratory shall successfully report the results for the blind EQAS samples in the FAT to WADA in accordance with ISL Art. 6.4 within five (5) working days of opening the samples, unless otherwise determined by WADA:

- Upon request, the probationary laboratory shall provide WADA with a Laboratory Documentation Package for selected EQAS samples for which there is an Adverse Analytical Finding. Additional data may be required upon WADA's request. This documentation shall be submitted within ten (10) working days of WADA's request or as otherwise indicated by WADA.
- For EQAS samples with Negative Findings, WADA may request all or a portion of the Initial Testing Procedure data.

4.4.1.1.6 After receiving the FAT EQAS results, WADA 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 WADA within thirty (30) calendar days, or as otherwise indicated by WADA.

4.4.1.1.7 WADA shall provide an Assessment Report with the outcomes of the accreditation assessment, including any identified nonconformities in order for the probationary laboratory to implement the necessary improvements. Corrective actions, if any, shall be conducted and reported by the probationary laboratory to WADA within thirty (30) calendar days, or as otherwise indicated by WADA. The nonconformities shall be satisfactorily addressed and the recommendations for improvement should be implemented before accreditation can be granted.

4.4.1.1.8 In order for a probationary laboratory to be considered for WADA accreditation, it shall have all mandatory Analytical Methods, as determined by WADA, validated and incorporated into its Scope of ISO/IEC 17025 Accreditation.

4.4.1.2 WADA Recommendation for Accreditation

~~Based on the audit, WADA will issue an Audit Report and submit this to the laboratory. If applicable, the laboratory shall correct identified non-compliances within defined time-frames and report these to WADA.~~

1.2.2—WADA report and recommendation

4.4.1.2.1 Based on the relevant documentation received from the probationary laboratory, the AuditAssessment Report(s) from WADA representative(s) and the Audit Report(s) and from the relevant accreditation body, WADA will Accreditation Body, the LabEG shall make a final report including a recommendation concerning the accreditation of the probationary laboratory. The report and

Once all accreditation requirements have been satisfactorily met by the probationary laboratory, the LabEG will submit its recommendation will be submitted to grant WADA accreditation of the laboratory to the WADA Executive Committee for approval. +-

However, if following the ease where FAT and on-site assessment, and the recommendation is review of any resulting Corrective Action Reports submitted by the probationary laboratory, the LabEG determines that the probationary laboratory should not be accredited, the laboratory will have a maximum of six (6) additional months to correct and improve specific parts of their operation, at which time a further report will be made by WADA any pending nonconformity(-ies). The provision of documentation, the analysis of additional EQAS samples and/or an additional on-site assessment, as determined by WADA, may be required and conducted at the probationary laboratory's expense. A probationary laboratory that fails to provide satisfactory improvements, as determined by the LabEG, after six (6) months may be required to renew its candidacy as described in ISL Art. 4.2 or to re-start the probationary phase of accreditation in accordance with ISL Art. 4.3.

4.4.1.2.2 Once a laboratory becomes a WADA-accredited laboratory, the new Laboratory shall, for a period of one (1) year, obtain a second opinion from an(other) Laboratory(-ies) before reporting any Adverse Analytical Finding or Atypical Finding. WADA may extend this requirement to obtain a second opinion beyond one (1) year.

4.1.10.4.1.3 Issuing and publishing of accreditation certificatePublishing of WADA Accreditation Certificate

A certificateAn Accreditation Certificate signed by a duly authorized representative of WADA shall be issued in recognition of anthe WADA accreditation. Such certificateAccreditation Certificate shall specify the name of the Laboratory and the period for which the certificateAccreditation Certificate is

valid. Accreditation Certificates may be issued after the effective date, with retroactive effect. A list of WADA-accredited Laboratories will laboratories shall be available published on WADA's website.

4.1.14.4.2 Maintaining WADA ~~accreditation~~ Accreditation

In order for the Laboratory to maintain its accreditation status, the *Anti-Doping Organization* of the country of the Laboratory (*National Anti-Doping Organization* and/or *National Olympic Committee* as applicable) shall be *Code* compliant (as determined by WADA) and the Laboratory host country shall maintain its status of a country having ratified the UNESCO Convention against Doping in Sport.

Should a Laboratory's accreditation be suspended in this context, the Suspension will be effective until the country ratifies the UNESCO Convention against Doping in Sport and/or until the non-compliant *Anti-Doping Organization* of the country of the Laboratory is taken out of the non-compliant list by WADA's Foundation Board. With the exception of the duration of the Suspension which shall be as defined above, the other ISL provisions with subject to the Suspension of a Laboratory's accreditation remain applicable.

WADA may decide not to suspend the Laboratory's accreditation in case of non-compliance of the *Anti-Doping Organization* of the country of the Laboratory if, in the year before the declaration of non-compliance, at least 60% of samples analyzed by that Laboratory were provided by *Anti-Doping Organizations* other than the *Anti-Doping Organization* of the country of the Laboratory, or if it is highly likely that in the year of the declaration of non-compliance at least 60% of samples analyzed by that Laboratory are going to be provided by *Anti-Doping Organizations* other than the *Anti-Doping Organization* of the country of the Laboratory.

~~Maintaining~~ In order to maintain WADA accreditation, a Laboratory shall comply with the following requirements.

4.1.14.4.2.1 Maintain ISO/IEC 17025 ~~accreditation~~ Accreditation

The Laboratory shall ~~hold an~~ maintain accreditation from the relevant accreditation body, ~~ILAC full member, signatory to ILAC MRA, according to ISO/IEC 17025,~~ with primary reference to the interpretations analysis of Samples (ISL Section 5), granted by a relevant Accreditation Body, which is an ILAC full member and applications of signatory to the ILAC MRA.

4.4.2.2 Flexible Scope of ISO/IEC 17025 requirements as described in the Application Accreditation

A Laboratory may modify or add Analytes to Analytical Testing Procedures, which are included within its Scope of ISO/IEC 17025 to the *Analysis of Urine Doping Control Samples* (Section 5.0) and the Application 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 Laboratory⁸.

The Flexible Scope of ISO/IEC 17025 Accreditation of Laboratories is not eligible for the following scenarios:

- 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 WADA prior to implementation by any Laboratory. WADA 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 WADA-organized EQAS round to evaluate whether the test is Fit-for-Purpose prior to the Analysis of Blood-Doping-Control providing approval. Before applying such a new Analytical Testing Procedure to the analysis of Samples (Section 6.0), as applicable, 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 a WADA EQAS, if available.
- WADA-specific Analytical Testing Procedures: WADA 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. Therefore, these Analytical Testing Procedures are not eligible for the analysis of Samples within a flexible Scope of ISO/IEC 17025 Accreditation. WADA will communicate which Analytical Testing Procedures are included in this category to the Laboratories and to the Accreditation Bodies. In such cases, the Analytical Testing Procedure shall be validated by the Laboratory, and the Laboratory may be required to successfully participate in an inter-laboratory collaborative study or WADA-organized EQAS round in order to obtain an extension to the Scope of ISO/IEC 17025 Accreditation by a relevant Accreditation Body before applying 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 under a Flexible Scope of ISO/IEC 17025 Accreditation.

4.4.2.2.1 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.

⁸ 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.

Laboratories are expected to include Analytical Testing Procedures within their Scope of ISO/IEC 17025 Accreditation prior to application to the analysis of *Samples*. Under exceptional circumstances, a Laboratory may apply an Analytical Testing Procedure (excluding any new or WADA-specific Analytical Testing Procedures, as defined above), 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 Analytical Testing Procedure 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 an Analytical Testing Procedure, which is not within the Laboratory's Scope of ISO/IEC 17025 Accreditation, may require the Laboratory to provide Analytical Method validation documentation or EQAS performance data in support of that *Adverse Analytical Finding*.

~~4.1.11.24.4.2.3~~ Participate in the WADA ~~External Quality Assessment Scheme~~EQAS Program

~~The WADA-accredited~~ Laboratories are required to ~~successfully~~ participate in the WADA EQAS which ~~is on a continuous basis and meet the performance requirements of the EQAS as~~ described in more detail in Annex A/SL Section 6.

4.4.2.4 Laboratory Independence and Impartiality

~~1.2.3~~—The Laboratory shall strictly maintain its full administrative and operational independence

~~The Laboratory shall be operationally independent from any Anti-Doping Organization to ensure full confidence in its competence, and impartiality, judgment or operational integrity, in compliance with section 4.1.5d of ISO/IEC 17025. Operational independence implies that the Laboratory shall have a separate budget permitting the Laboratory to manage its own affairs without hindrance or interference at all times (see ISL Art. 4.2.3) ⁹.~~

~~4.1.11.34.4.2.5~~ Documenting complianceDocument Compliance with the WADA Laboratory Code of Ethics

The Laboratory shall annually provide to WADA a letter of compliance with the provisions of the Code of Ethics ~~(Annex B)~~, signed by the Laboratory Director. ~~All staff employed at the Laboratory, permanent~~

⁹ Laboratories shall comply with the requirements of administrative and operational independence established in ISL Art. 4.4.2.4 (with reference to ISL Art. 4.2.3) within two (2) years after the effective date of this ISL version 10.0.

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 ~~(Annex B)~~.

~~1.2.4—Documenting implemented research and development activities~~

~~The Laboratory shall establish a system requiring Laboratory staff to report any breaches of the Code of Ethics identified by the Laboratory, either to the Laboratory Director or directly to WADA (if there are suspicions that the Laboratory Director may be complicit or implicated in unethical conduct). The Laboratory Director and/or WADA, respectively, shall immediately and thoroughly investigate any alleged breach of the Code of Ethics.~~

~~If the Laboratory's investigation determines that a breach of the Code of Ethics occurred, the Laboratory Director shall immediately inform WADA of the results of the investigation and the disciplinary actions taken. WADA may also request further sanctions or implement sanctions as a result of its own investigations. Sanctions 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) or even the Suspension or Revocation of the Laboratory's WADA accreditation.~~

~~4.4.2.6 Document Implemented Research and Development Activities~~

The Laboratory shall maintain a plan for research and development in the field of ~~Doping Control~~anti-doping science, including an annual budget in this area of at least 7% of the total annual ~~budget~~operational budget allocated to activities associated with Code-compliant Anti-Doping Organizations.

The Laboratory should document the publication of results of the research in relevant scientific papers in the peer-reviewed literature (at least one publication every two years~~—~~)¹⁰. The list of scientific papers shall be made available to WADA upon request. The Laboratory may also demonstrate a research program by documenting successful or pending applications for research grants ~~(at least one (1) application submitted every three (3) years—)~~.

The Laboratory shall supply an annual progress report to WADA documenting research and development results in the field of ~~Doping Control and dissemination of the results~~anti-doping science. The Laboratory ~~should~~shall also relate research and development plans for the ~~next~~following year.

~~1.2.5—Documenting implemented sharing of knowledge~~

~~4.4.2.7 Document Implemented Sharing of Knowledge~~

¹⁰ 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.

The Laboratory shall demonstrate its willingness and ability to share knowledge with other ~~WADA-accredited Laboratories~~. The Laboratory shall disseminate the results of its research and development activities to other Laboratories. The Laboratory should 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.

The Laboratory shall supply an annual report on sharing of knowledge with ~~all other WADA-accredited Laboratories to WADA~~. A description of ~~this~~ sharing of knowledge is provided in the Code of Ethics (ISL Annex BA).

~~1.2.6—Maintaining professional liability insurance coverage~~

4.4.2.8 Maintain Professional Liability Insurance Coverage

Laboratories shall provide documentation to WADA that professional liability risk insurance coverage is maintained ~~to an amount of~~ no less than two (2) million USD annually.

~~1.2.7—Providing renewed letter(s) of support~~

~~Letter(s) of support, as described in Section 4.1.3, from a National Anti-Doping Organization or National Olympic Committee responsible for a national Doping Control program or an International Federation responsible for an international Doping Control program shall be provided to WADA every two years confirming three years of support or unless otherwise approved by WADA.~~

4.4.11.44.2.9 Maintain Minimum ~~number~~ Number of Samples

In order to maintain proficiency, ~~WADA-accredited in Analytical Testing~~, Laboratories are required, ~~within two years of the effective date of the current version of the ISL,~~ to analyze a minimum of ~~3000 Doping Control~~ 3,000 Samples¹¹ provided annually by Signatory, Code-compliant Testing Authorities/Anti-Doping Organizations (as determined by WADA) or as otherwise approved by WADA.

WADA will monitor the number of Samples tested by the Laboratory. If the number of Samples falls below ~~3000~~ 3,000 per year, ~~the Laboratory's WADA Laboratory accreditation may be suspended or revoked~~ in accordance with ~~sections~~ ISL Art. 4.6.4.13.1.2-1, 4.4.13.2.2 and 4.4.14.

When an Anti-Doping Organization is declared non-compliant with the Code by WADA, it is recognized that this may affect a Laboratory's ability to analyze a minimum of 3,000 Samples annually. In such cases,

¹¹ To determine the minimum number of Samples, each urine Sample, blood Sample and ABP blood Sample analyzed by the Laboratory shall count as an individual Sample.

WADA shall require that the Laboratory implements measures to maintain proficiency in Analytical Testing, for example by strengthening its internal Quality Assurance Scheme (iQAS) and internal audits program. WADA may also provide additional EQAS samples and/or conduct a document audit and/or an on-site assessment, at its discretion, in order to assess the status of the Laboratory's operations.

4.1.11.54.4.2.10 Publication of ~~fee schedule~~ Fee Schedule

To assist ~~Anti-Doping Organizations~~ Testing Authorities in developing Test Distribution Plans in relation to the use of different ~~Sample analysis~~ Analytical Testing menus for various sports or sport disciplines, Laboratories shall ~~publish, and provide to WADA, the most recent~~ report into ADAMS an up-to-date price list for each type of ~~analytical method~~ Analytical Method or service that is available to the Anti-Doping Organizations.

~~4.2.8~~ **Participating in WADA/ Accreditation Body reRe-assessments and surveillance assessments**

~~4.1.11.6.4.2.11~~ WADA reserves the right to inspect and assess the Laboratory at any time. The notice of the assessment/inspection will be made in writing to the Laboratory Director. In exceptional circumstances, Continuous Assessments during the assessment/inspection may be unannounced Accreditation Cycle

~~4.1.11.6.4.2.11.1.4-4.11.1~~ WADA/ Accreditation Body reRe-assessment and/or Continuous Assessment during the Accreditation Cycle

~~The Laboratory shall receive ISO/IEC 17025 accreditation including compliance with the Application of ISO/IEC 17025 for the Analysis of Urine Doping Control Samples (Section 5.0) and Application of ISO/IEC 17025 for the Analysis of Blood Doping Control Samples (Section 6.0), as applicable. The assessment team shall include at least one ISL-trained assessor selected by the accreditation body Accreditation Body for the on-site assessment/rere-assessment.~~

~~Copies~~ The relevant Accreditation Body should send copies of the rere-assessment summary report of the Assessment Report, in English or French, as well as the Laboratory responses should be sent in a timely fashion to WADA by the relevant accreditation body. Should the Laboratory prefer to provide the rere-assessment Assessment Report summary report directly to WADA, then it shall do so within thirty (30) calendar days from receiving the Accreditation Body's Assessment Report.

~~The Laboratory shall provide to WADA a with an updated copy of the ISO/IEC 17025 certificate Certificate and Scope of ISO/IEC 17025 Accreditation as soon as it is obtained from the relevant accreditation body Accreditation Body.~~

~~4.4.11.2~~ Accreditation Body surveillance assessment

~~When a surveillance ISO/IEC 17025 assessment is required, a copy of the assessment summary report and evidence of corrective actions for any non-compliance(s), in English or French, should be sent to WADA by the relevant accreditation body. Should the Laboratory prefer to provide the assessment summary report directly to WADA, then it shall do so within 30 days.~~

~~4.4.11.3~~ WADA assessment

4.4.2.11.2 WADA Assessment

WADA reserves the right to conduct document-based audits as well as inspect and assess the Laboratory through on-site assessments at any time, at WADA's expense. The notice of the assessment will be made in writing to the Laboratory Director. In exceptional circumstances, and at WADA's discretion, the on-site assessment may be unannounced.

As part of an announced or unannounced Laboratory on-site assessment/inspection, WADA retains the right to request copies of Laboratory documentation and/or request ~~re-analysis~~ Further Analysis of selected "A" and/or "B" Samples either on-site or in ~~another~~ Laboratory of WADA's choice.

1.2.9—Flexible Scope of Accreditation

~~WADA-accredited Laboratories may modify or add analytes to existing scientific methods to expand their scope or develop new methods that involve technology already within the scope of accreditation without the need for approval(-ies) chosen by the body that completed the ISO/IEC 17025 accreditation of that Laboratory. Any new analytical method or procedure to Doping Control requiring expertise and technology outside the Laboratory scope of accreditation shall be properly validated by the Laboratory and be determined as Fit for purpose by WADA prior to first implementation by any Laboratory into the field of anti-doping analysis. WADA shall use whatever means deemed appropriate, including formal consultations with scientific expert working groups, and/or publication(s) in peer reviewed scientific journal(s) to evaluate whether the test is Fit for purpose prior to providing approval. Before applying such a new method or procedure to the analysis of Doping Control Samples, but after the approval by WADA, the Laboratory shall obtain an extension of the scope of accreditation by a relevant accreditation body. WADA.~~
Inclusion of a method or procedure within the Laboratory's scope of ISO/IEC 17025 accreditation establishes that method or procedure as Fit for purpose and the Laboratory shall not be required to provide method validation documentation in support of an Adverse Analytical Finding.

1.2.10—WADA monitoring of accreditation status

4.5—WADA shall conduct a periodic Removal of Samples

4.5.1 Removal of Samples for Further Analysis

Within the context of an investigation or Laboratory performance monitoring activity (for example, during an on-site Laboratory assessment), WADA, initially at its expense¹², may remove Sample(s) stored in a Laboratory in order to conduct Further Analysis for the purpose described in Code Art. 6.2. In such cases, WADA shall notify the Testing Authority and Results Management Authority, which shall retain ownership

¹² If Laboratory nonconformities are revealed with respect to the Analytical Testing of any Sample, WADA retains the right to recover the expenses incurred in connection with the Further Analysis of the Samples from the Laboratory.

of the *Sample(s)* pursuant to ISTI Art. 10.1. Notwithstanding the aforementioned, *WADA* shall retain the right to request Further Analysis, at its expense, as permitted by *Code* Art. 6.5, Para. 2.

WADA may delegate an observer to monitor the removal of the *Samples*, which shall be implemented in accordance with *WADA*'s instructions. During the removal of *Samples*, *WADA* 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).

WADA 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).

4.5.2 Removal of *Samples* for Laboratory Quality Assessment

WADA may also direct the re-analysis of anonymized *Samples*, which have met the conditions described in ISL Art. 5.3.3.1, for purposes of Laboratory quality assurance and education, including the implementation of a system of transfer of *Samples* reported as Negative Findings between Laboratories¹³. In this regard, the number of *Samples* directed by *WADA* for re-analysis may vary but shall be guided by the criteria established in ISL Art. 6.2.1.1.

4.6 *WADA* Monitoring of Accreditation Status

WADA shall regularly review ~~of the~~ compliance of Laboratories ~~against with~~ the requirements listed in the ISL- and related Technical Documents and Technical Letters. In addition, *WADA* shall also conduct an annual review of EQAS results and ~~of~~ relevant routine ~~testing~~ *Analytical Testing* issues ~~(see Section 5.0 and/or Section 6.0)~~ reported to *WADA* by stakeholders to assess the overall performance of each Laboratory and to decide its accreditation status.

~~4.1.124.6.1~~ ~~4.4.13.1~~ Maintenance of ~~accreditation~~ *WADA* Accreditation

~~In Compliance with all the event that the requirements established in ISL Art. 4.4.2, including satisfactory performance by a Laboratory has performed satisfactorily in the *WADA* EQAS (Annex A) and in routine operations, Analytical Testing (see ISL Sections 6 and 7), as determined by *WADA*, is a critical requirement for the maintenance of the Laboratory's *WADA* will maintain the accreditation of the Laboratory.~~

4.6.2 Re-accreditation Costs

On an annual basis, *WADA* will invoice the Laboratory for a portion of the costs associated with the re-

¹³ A transfer of *Samples* with Negative Findings shall apply only to *Samples* from Testing Authorities which are Code-compliant Anti-Doping Organizations.

accreditation process.4.4.13.2

4.6.3 Issuing and Publication of Accreditation Certificate

On an annual basis, when maintenance of accreditation is approved, the Laboratory shall receive a WADA Accreditation Certificate, signed by a duly authorized representative of WADA, which is issued in recognition of such accreditation. The Accreditation Certificate shall specify the name of the Laboratory and the time period for which the Accreditation Certificate is valid. WADA Accreditation Certificates may be issued after the effective date, with retroactive effect. The list of WADA-accredited Laboratories is maintained on WADA's website.

4.1.134.6.4 Loss of ~~accreditation~~ WADA Accreditation

~~Loss of A Laboratory's WADA accreditation may occur be suspended or revoked, or subject to an Analytical Testing Restriction, whenever WADA has justified reason to believe that the Laboratory fails to comply with the ISL and/or Technical Documents and/or Technical Letters, or where the Suspension of, Revocation of accreditation is or Analytical Testing Restriction is otherwise required in order to protect the integrity of the Samples, the Analytical Testing process or the interests of the Anti-Doping Community.~~

4.6.4.1 ~~4.4.13.2.1~~ Suspension of Accreditation and Analytical Testing Restriction

~~The Chairman of the WADA Executive Committee may suspend a Laboratory's WADA accreditation or impose an Analytical Testing Restriction against a Laboratory if WADA identifies a noncompliance with the ISL and/or Technical Documents and/or Technical Letters based on the Laboratory's performance during the EQAS or during routine Analytical Testing.~~

4.6.4.1.1 Suspension of Accreditation and Analytical Testing Restriction – No Disciplinary Proceedings

~~In the event that a Laboratory has accumulated the maximum allowed number of penalty points for the EQAS and/or Analytical Testing (as determined by the application of the ISL Points Scale Table in ISL Art. 7.3), or that a Laboratory has reported a False Adverse Analytical Finding with Consequence(s) for the Athlete, the LabEG will make a recommendation to the Chairman of the WADA Executive Committee that the Laboratory be subject to an Analytical Testing Restriction or Suspension, as applicable. In such circumstances, the Laboratory has no right to appeal the recommendation of the LabEG to the Disciplinary Committee before the decision is rendered by the Chairman of the WADA Executive Committee.~~

4.6.4.1.2 Suspension of Accreditation and Analytical Testing Restriction – Disciplinary Proceedings

~~The LabEG may recommend to the Chairman of the WADA Executive Committee that a Laboratory be subject to an Analytical Testing Restriction or a Suspension of its WADA accreditation may be based on even if the Laboratory has not reported a False Adverse Analytical Finding with Consequence(s) for an Athlete or has not attained the maximum number of penalty points detailed in the ISL Points Scale Table in ISL Art. 7.3, but not limited to, the where the Laboratory's other Analytical Testing failure(s) and/or other identified nonconformities (as described in ISL Art. 4.6.4.2) otherwise justifies that such action be taken to ensure the full reliability and accuracy of Analytical Testing and the accurate reporting~~

~~of test results of the EQAS (as per Annex A) or other evidence of serious ISL deviation(s) arising from the routine analysis of *Doping Control Samples*.¹⁴.~~

~~The following ISL non-compliances in the routine operations of a Laboratory may be considered and include, but are not limited to:~~

~~Suspension~~In such cases, the Laboratory and the WADA LabEG shall participate in the resolution facilitation session foreseen in ISL Art. 4.6.4.4, at the conclusion of which the Laboratory may accept the LabEG's recommendation and the terms of the LabEG's Analytical Testing Restriction or Suspension. As indicated in ISL Art. 4.6.4.4, the Chairman of the WADA Executive Committee must approve any agreement between the Laboratory and WADA regarding the Laboratory's accreditation status and the terms of its Analytical Testing Restriction or Suspension.

~~However, if the Laboratory does not accept the LabEG's recommendation and/or the terms of the LabEG's Analytical Testing Restriction or Suspension following the resolution facilitation process as per ISL Art. 4.6.4.4, the Laboratory may appeal the LabEG's recommendation to the Disciplinary Committee and disciplinary proceedings will be conducted in accordance with ISL Art. 4.6.4.5.~~

~~In such circumstances, the LabEG may, on the basis of the seriousness of the Laboratory's Analytical Testing failures and/or other identified nonconformities, recommend to the Chairman of the WADA Executive Committee that the Laboratory:~~

- ~~- May continue its Analytical Testing activities pending the outcome of the Laboratory's appeal to the Disciplinary Committee; or~~
- ~~- Be immediately subject to a provisional Analytical Testing Restriction or that its WADA accreditation be immediately suspended on a provisional basis pending the outcome of the Laboratory's appeal to the Disciplinary Committee. In such cases, a decision by the Chairman of the WADA Executive Committee to provisionally suspend the Laboratory's WADA accreditation or subject the Laboratory to a provisional Analytical Testing Restriction shall not be subject to appeal by the Laboratory.~~

~~However, should the Laboratory be immediately subject to a provisional Analytical Testing Restriction or should its WADA accreditation be immediately suspended on a provisional basis, the Laboratory's appeal to the Disciplinary Committee shall be heard within thirty (30) calendar days of the date of the imposition~~

¹⁴ If WADA determines that the noncompliance(s) leading to the Suspension of the Laboratory's WADA accreditation or that the imposition of an Analytical Testing Restriction against the Laboratory does not affect the Laboratory's ability to analyze blood Samples for the ABP or to operate as an APMU, then the Laboratory may, at WADA's discretion, continue operating in such a capacity. In such cases, WADA will inform the Laboratory accordingly.

of the provisional Analytical Testing Restriction or the Provisional Suspension of the Laboratory's WADA accreditation.

4.6.4.2 Noncompliances with the ISL

Noncompliances with the ISL include, but are not limited to:

- Suspension, or withdrawal of ISO/IEC 17025 accreditation;
- Repeated reporting of False Adverse Analytical Findings and/or False Negative Findings¹⁵:
 - The reporting of two (2) or more independent ¹⁶ False Adverse Analytical Finding per EQAS round;
or
 - The reporting of three (3) or more independent ¹⁶ False Adverse Analytical Findings, including EQAS and routine Analytical Testing, per 12-month period; or
 - The reporting of three (3) or more independent ¹⁶ False Negative Findings per EQAS round; or
 - The reporting of four (4) or more independent ¹⁶ False Negative Findings, including EQAS and routine Analytical Testing, per 12-month period; or
 - Any combination of four (4) or more independent ¹⁶ False Adverse Analytical Findings and False Negative Findings, including EQAS and routine Analytical Testing, per 12-month period.
- Failure to comply with any of the requirements or standards listed in the ISL and/or Technical Documents and/or Technical Letters;
- Serious and repeated noncompliances with results reporting timelines (see ISL Arts. 5.3.5.2.5 and 5.3.5.2.7.3);
- Failure to take appropriate corrective action after an unsatisfactory performance ~~withinduring~~ routine Analytical Testing or in ~~ana~~ blind EQAS or double-blind EQAS round;
- Failure to ~~comply with any of the requirements or standards listed in WADA~~ take appropriate corrective action for ISL and/or Technical Documents; Document and/or Technical Letter noncompliance(s) identified from Laboratory on-site assessment(s);
- Failure to cooperate with WADA or the relevant Testing Authority or Results Management Authority in providing documentation;
- ~~Non-compliance~~ Noncompliance(s) with the WADA Laboratory Code of Ethics;

¹⁵ LabEG recommendations are made in consideration of the number of false analytical findings reported by the Laboratory, irrespective of the total number of penalty points accumulated during this period (*i.e.* after consideration of any applicable penalty point deductions) or whether or not the Laboratory has satisfactorily corrected the noncompliances.

¹⁶ Independent analytical findings are produced by different and unrelated root causes and based on a satisfactory Root Cause Analysis investigation, as determined by the WADA LabEG.

- Laboratory staff and/or management issues, including but not limited to:
 - Major changes in key staff senior Laboratory management positions (e.g. Laboratory Director, Quality Manager) without proper and timely notification to WADA;
 - Failure to appoint a permanent Laboratory Director or other senior management positions (e.g. Quality Manager) within a reasonable timeline;
 - Failure to guarantee the competence and/or proper training of scientific staff, including, for example, the qualification of analysts as Certifying Scientists and Laboratory Supervisory Personnel (see ISL Arts. 5.2.2.6 and 5.2.2.7);
 - Significant loss or lack of experienced staff (e.g. Certifying Scientists) that affects, as determined by WADA, the Laboratory's ability to ensure the full reliability and accuracy of Analytical Testing and reporting of test results;
 - Loss of sufficient Laboratory support and resources that affects, as determined by WADA, the quality and/or viability of the Laboratory;
 - Failure to analyze the minimum number of Samples indicated in ISL Art. 4.4.2.9; or
 - Failure to cooperate in any WADA enquiry in relation to the activities of the Laboratory:
 - Non-compliance(s) identified from Laboratory on-site assessment(s);
 - Loss of support jeopardizing the quality and/or viability of the Laboratory;

~~Non-compliance(s) in Laboratory routine performance will be assessed by WADA on a case-by-case basis considering the severity and consequences to the Anti-Doping System. If evidence of serious or multiple non-compliance(s) exists, WADA reserves the right to provisionally suspend a Laboratory's accreditation pending a full investigation. Such a decision may be taken by the Chairman of the WADA Executive Committee.~~

~~The period and terms of Suspension shall be proportionate to the seriousness, as determined by the investigation, of the non-compliance(s) or lack of performance and the need to ensure accurate and reliable drug testing of Athletes. A period of Suspension shall be of a duration to be decided by WADA and up to a maximum of six months, during which time any non-compliance must be corrected, documented and reported to WADA. If the non-compliance(s) cannot be corrected during the initial Suspension period, the Suspension shall either be further extended or the Laboratory accreditation revoked. The Suspension period may be extended up to a maximum of an additional six months, based on justifiable delays in submitting the satisfactory corrective actions. If the Laboratory has provided evidence determined to be satisfactory by WADA that the non-compliance(s) are corrected, the Laboratory's accreditation shall be re-instated. If the Laboratory has not provided evidence determined to be satisfactory by WADA at the end of the~~

~~extended Suspension period, not to exceed 12 months, the Laboratory's accreditation shall be revoked.~~

~~If applicable, a delay in the delivery of the ISO/IEC 17025 accreditation to the Laboratory by the relevant accrediting body may also extend the WADA Suspension.~~

~~A Laboratory whose accreditation has been suspended is ineligible to perform testing of Doping Control Samples for any Testing Authority, except when the non-compliance(s) is restricted to a particular analysis. In this case, WADA may suspend the Laboratory from performing that specific analysis. If WADA determines that the non-compliance(s) is limited to a class of Prohibited Substances or a specific analytical method, WADA may limit the Suspension to analysis for the class of compounds or analytical method in which the non-compliance(s) occurred.~~

~~During the Suspension of the Laboratory, WADA may require the Laboratory to successfully analyse blind EQAS samples and/or require an on-site assessment by WADA, at the expense of the Laboratory, in order to evaluate the Laboratory's status.~~

4.6.4.13.2-2-3 Revocation of accreditation~~Accreditation~~

The WADA Executive Committee shall revoke the WADA accreditation of any Laboratory~~accredited under these provisions~~ if it determines that Revocation is necessary to ensure the full reliability and accuracy of Analytical Testing and the accurate reporting of analytical test results. Revocation of accreditation may be based on, but not limited to, the following considerations in the EQAS analysis and/or routine operation of a Laboratory:

Reporting~~Revocation~~ of WADA accreditation may be based on, but not limited to, the following noncompliance(s):

- Repeated reporting of False Adverse Analytical Findings or repeated failure to take appropriate corrective action after the reporting of a False Adverse Analytical Finding;
 - ~~Loss of ISO/IEC 17025 accreditation;~~
- Repeated Suspensions of Repeated reporting of False Negative Findings or repeated failure to take appropriate corrective action after the reporting of False Negative Finding(s);
- Repeated suspensions of ISO/IEC 17025 accreditation or Suspensions of WADA accreditation or repeated impositions of Analytical Testing Restrictions against the Laboratory;
- Systematic Failure to correct a noncompliance with any of the requirements or standards listed in the ISL and/or Technical Documents and/or Technical Letters by the end of the Suspension period or at the end of an extension of the Suspension period in accordance with ISL Art. 4.6.6.1;

- Repeated failure to comply with the ISL and/or Technical Documents and/or Technical Letters;
- Serious Laboratory non-compliance(s) with the ISL and/or Technical Documents and/or Technical Letters identified ~~(e.g., for example, during on-site assessments, by documented client complaints, or through other enquiries)~~ as determined or investigations conducted by WADA;
- Repeated failure to take appropriate corrective action following unsatisfactory performance either in routine Analytical Testing or in a blind EQAS or double-blind EQAS round(s);
- ~~A serious or repeated non-compliance(s) with the Repeated failure to take appropriate corrective action following ISL and/or Technical Document and/or Technical Letter noncompliance(s) identified from Laboratory on-site assessment(s);~~
 - ~~Failure to correct a lack of compliance with any of the requirements or standards listed in the WADA ISL (including Annex A External Quality Assessment Scheme) during a Suspension period;~~
 - ~~Non-compliance with the WADA External Quality Assessment Scheme requirements as defined in Annex A;~~
- Repeated failure to analyze the minimum number of Samples indicated in ISL Art. 4.4.2.9;
- Continuous, serious Laboratory staff and/or management issues (e.g. continuous turnover of qualified staff affecting Laboratory expertise and competence, inadequate training, repeated failure to train and qualify an appropriate number of analysts as Certifying Scientists);
 - ~~Failure to cooperate with WADA or the any relevant Testing Authority during the Suspension phase;~~
- ~~Failure to inform clients of Suspension a period of accreditation~~ Suspension or following the imposition of an Analytical Testing Restriction;
- Analysis of Samples from Signatories in violation of a Suspension or Analytical Testing Restriction decision;
- A serious or repeated violation(s) of the Code of Ethics;
 - ~~Conviction of any key personnel for any criminal offence committed that is related to the operation of the Laboratory;~~
- ~~Any other cause that materially affects the ability of the Laboratory determined by WADA to ensure the full reliability and accuracy of drug tests and the accurate reporting impact the operations of results the Laboratory;~~
- Repeated and/or continuous failure to cooperate in any WADA inquiry in relation to the activities of the Laboratory;
- Failure to maintain administrative and operational independence as described in ISL Art. 4.4.2.4;
- Loss of support ~~jeopardizing which significantly affects~~ the quality and/or viability of the Laboratory; and

- ~~The~~ 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 a false ~~Adverse Analytical Finding~~ on a routine ~~Sample~~ test results.

4.6.4.4 Resolution Facilitation

Prior to the commencement of Disciplinary Proceedings in accordance with ISL Arts. 4.6.4.1.2 and 4.6.4.5, the WADA LabEG, upon request by the Laboratory Director, will hold a resolution facilitation session with the Laboratory Director (via teleconference or other means). During this session, the LabEG shall explain the Laboratory's noncompliances with the ISL and/or Technical Document(s) and/or Technical Letter(s) and offer the Laboratory Director an opportunity to provide further clarification to the WADA LabEG.

During this resolution facilitation session, the Laboratory and the WADA LabEG may agree to the terms and duration of the Suspension of the Laboratory's WADA accreditation or the terms of the Laboratory's Analytical Testing Restriction. Any such agreement must be submitted to the Chair of the WADA Executive Committee for approval. Following such approval by the Chair of the WADA Executive Committee, Disciplinary Proceedings will not be instituted against the Laboratory.

Should the Laboratory and the WADA LabEG be unable to come to an agreement regarding the terms and duration of the Suspension of the Laboratory's WADA accreditation or the terms of the Laboratory's Analytical Testing Restriction during the resolution facilitation session, the procedure as per ISL Art. 4.6.4.5 shall be followed.

4.6.4.5 Disciplinary Proceedings

In the event that the Laboratory decides to appeal the LabEG's recommendation to impose an Analytical Testing Restriction or to suspend its WADA accreditation in accordance with ISL Art. 4.6.4.1.2 or should a Laboratory's WADA accreditation be subject to Revocation in accordance with ISL Art. 4.6.4.3, WADA shall constitute an impartial Disciplinary Committee (DC) in accordance with Art. 1 of the Procedural Rules (ISL Annex B). The DC shall be responsible for conducting Disciplinary Proceedings in accordance with the Procedural Rules.

In such circumstances, WADA shall provide the DC with a serious non-conformity. The following case file, which shall include the relevant documentation and correspondence related to the Laboratory's Analytical Testing failures or other ISL noncompliances or, where applicable, the circumstances that have resulted in the Laboratory's WADA accreditation being subject to Revocation proceedings. The Laboratory shall be permitted to make written submissions and provide any supporting documents or evidence in accordance with Art. 3 of the Procedural Rules (ISL Annex B).

The DC shall issue a recommendation to the Chair of the WADA Executive Committee or, where applicable, to the WADA Executive Committee, regarding the action(s) to be taken with regard to the Laboratory's WADA accreditation in accordance with the requirements and procedure described in Art. 7 of the Procedural Rules (ISL Annex B).

4.6.4.6 Notification of Decision

Upon completion of the procedures ~~are to be followed~~ indicated in ISL Arts. 4.6.4.5 or 7.3, as applicable, and in accordance with the timelines indicated in Art. 7 of the Procedural Rules (ISL Annex B), WADA shall provide the Laboratory with written notice of its decision regarding the status of the Laboratory's WADA accreditation. This notice shall state the following:

The ~~Laboratory shall~~ 1) That the Laboratory's WADA accreditation has been maintained (including warnings, if applicable); or

2) That the Laboratory's WADA accreditation has been suspended or revoked or that an Analytical Testing Restriction has been imposed against the Laboratory.

Such notice shall include:

- The reason(s) for Suspension or Revocation or the imposition of an Analytical Testing Restriction;
- The terms of the Suspension, Revocation, or Analytical Testing Restriction; and
- The period of Suspension or of Analytical Testing Restriction, if applicable.

For proceedings conducted pursuant to ISL Art. 4.6.4.5, WADA shall also provide the Laboratory with a copy of the DC's recommendation regarding the Suspension or Revocation of the Laboratory's WADA accreditation or the imposition of an Analytical Testing Restriction against the Laboratory.

4.6.4.7 Effective Date and Appeals

A Suspension or Analytical Testing Restriction is effective immediately ~~notify WADA if any result upon~~ receipt of notification of the decision.

A Revocation takes effect one (1) month after notification. The Laboratory shall remain under Suspension until such a time when the Revocation becomes effective or pending the outcome of any possible appeal of the Revocation decision by the Laboratory.

A Laboratory may appeal a decision by WADA to revoke or suspend its WADA accreditation, or to impose an Analytical Testing Restriction, to CAS in accordance with Code Art. 13.7. The Laboratory shall have twenty-one (21) calendar days ~~from a Sample~~ the date of receipt of the decision from WADA to file an appeal to CAS.

4.6.4.8 Public Notice

WADA shall announce a change in a Laboratory's accreditation status on its website as soon as the Laboratory is notified by WADA of its decision. The public notice shall include the name and address of any Laboratory that has had its accreditation suspended or revoked or that has been subjected to an Analytical Testing Restriction, as well as the name of any Laboratory that has had its Suspension or Analytical Testing Restriction lifted. In cases of Laboratory Revocation, the public notice shall specify that

the Laboratory shall remain under Suspension until the date when the Revocation becomes effective, as determined in ISL Art 4.6.4.7.

WADA shall also indicate the terms and length of the Suspension or the Analytical Testing Restriction, as well as the nature of the Laboratory's noncompliance with the ISL and/or Technical Document(s) and/or Technical Letter(s).

WADA's website shall be updated regarding a Laboratory's accreditation status.

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4.6.5 Consequences of Suspended or Revoked Accreditation or Analytical Testing Restriction

4.6.5.1 Analytical Testing Restriction

If WADA determines that the noncompliance(s) are limited to a class of *Prohibited Substances* or *Prohibited Methods* or to a specific Analytical Testing Procedure, WADA will 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.

The Laboratory shall inform its clients of the imposed Analytical Testing Restriction and shall subcontract the affected analyses to another Laboratory(-ies) during the period of the Analytical Testing Restriction, as provided in ISL Art. 5.4.8. A Laboratory under an Analytical Testing Restriction shall inform WADA of the identity of the relevant Testing Authority(-ies) and the chosen Laboratory(-ies).

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.

The Laboratory shall transfer¹⁷ the following *Samples* ("A" and "B" *Samples*) in the Laboratory's custody, which involve the analysis of the same class of *Prohibited Substances* or *Prohibited Methods* and/or the application of the affected Analytical Testing Procedure(s) subjected to the Analytical Testing Restriction, to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures (unless otherwise instructed by WADA):

- ~~*Samples, which had been previously reported as an Adverse Analytical Finding to an Anti-Doping Organization. WADA may provisionally suspend the Laboratory pending resolution of the case.*~~
- ~~The responsible Laboratory shall be immediately notified by WADA if it is determined that a false *Adverse Analytical Finding* has been reported. WADA may provisionally suspend the Laboratory pending resolution of the case.~~
- ~~The Laboratory is to provide WADA with a satisfactory root cause analysis report including the reason(s) for the error within five calendar days (unless informed otherwise by WADA). Supporting documentation shall be provided such as all quality control data from the batch of routine *Samples* that included the false *Adverse Analytical Finding* sample (particularly if the error is deemed to be technical/scientific).~~

¹⁷ The Laboratory under Analytical Testing Restriction shall contact the relevant Testing Authority(-ies) to arrange for the transfer of the relevant *Samples* to subcontracted Laboratory(-ies), chosen by the Testing Authority, within thirty (30) calendar days of being notified of the Analytical Testing Restriction decision. All associated costs shall be borne by the Laboratory under Analytical Testing Restriction.

- ~~WADA shall review the Laboratory's explanation promptly;~~

- ~~The Laboratory may be required to review past test Samples, which have been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Analytical Testing Restriction decision;~~

- ~~Samples for which the "A" or "B" Confirmation Procedures had been completed, but results and may be required to re-analyze all relevant Samples reported as Adverse Analytical Findings by the Laboratory from of the analysis had not been reported by the Analytical Testing Restriction date, or Samples which had been undergoing "A" or "B" Confirmation Procedures at the time of final resolution; the imposition of the error to the previous 12 months or satisfactory EQAS round, if applicable. Depending Analytical Testing Restriction;~~

- ~~Samples which have been reported as an Adverse Analytical Finding based on the type "A" Confirmation Procedure prior to the imposition of error that caused 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 false Adverse Analytical Finding, this retesting may be limited to one analyte, one or more substance(s) or a period of the Analytical Testing Restriction, both "A" and "B" Samples shall be transferred¹⁷ to another Laboratory(-ies) for the "A" Confirmation Procedure to be performed again and for the performance of the "B" Confirmation Procedure, if applicable.~~

~~If the Analytical Testing Restriction has been 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 Testing Authority and WADA. In such cases, both the "A" and "B" containers of the relevant Samples shall be transferred¹⁷ to another Laboratory(-ies) for Further Analysis, as determined by WADA. These re-analyses may be applied to the class of Prohibited Substances and/or Prohibited Methods. A statement signed or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by the Laboratory Director shall document this re-testing. The WADA.~~

4.6.5.2 Suspension

~~A Laboratory will be required to notify all clients whose WADA accreditation has been suspended is ineligible to perform Analytical Testing of Samples for any Code-compliant Anti-Doping Organization. This provision does not apply when the noncompliance(s) that led to the Suspension do not affect the blood analyses for the ABP, as determined by WADA.~~

~~4.6.5.2.1 If the reason for the Suspension was related to a violation of the Code of Ethics (Annex A), all Analytical Testing in the suspended Laboratory shall cease immediately and the Laboratory shall~~

transfer ¹⁸ all *Samples* (both the “A” and “B” *Samples*) in the Laboratory’s custody to other Laboratory(-ies) chosen by the Testing Authority(-ies).

4.6.5.2.2 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 ¹⁸ 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 WADA:

- *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;
- *Samples* for which Initial Testing Procedures had been completed and produced Presumptive *Adverse Analytical Finding(s)*, but for which Confirmation Procedures had not yet been performed at the time of the Suspension;
- *Samples*, which have been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Suspension;
- *Samples* which have been received at the Laboratory but not 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 ¹⁸ to another Laboratory(-ies)].
- *Samples* for which “A” or “B” Confirmation Procedures had been completed, but results may have been affected by the error in accordance of the analysis had not been reported by the Suspension date, or *Samples* which had been undergoing “A” or “B” Confirmation Procedures at the time of the Suspension;
- *Samples* which have been reported as an *Adverse Analytical Finding* based on the “A” Confirmation Procedure prior to the Suspension.

4.6.5.2.3 A Laboratory that has had its WADA 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

¹⁸ The suspended or revoked Laboratory shall contact the relevant Testing Authority(-ies) to arrange for the transfer of *Samples* to Laboratory(-ies), chosen by the Testing Authority, within thirty (30) calendar days of being notified of the Suspension or Revocation decision. Any additional costs of analysis to those previously agreed or already paid to the suspended or revoked Laboratory shall be borne by the Laboratory under Suspension or Revocation. In case of Code of Ethics violation(s), the suspended or revoked Laboratory shall also reimburse the Testing Authority for the costs of re-analyses in another Laboratory. The suspended or revoked Laboratory shall inform WADA of such actions including providing the *Sample* code(s) and the identity of the relevant Testing Authority(-ies) and the chosen Laboratory(-ies). Testing Authorities should consider differences in analytical capacity between the suspended or revoked Laboratory and the receiving Laboratory(-ies) (e.g. LOI for Non-Threshold Substances, capacity to perform specific analyses). In such cases, the Testing Authority may consult the Laboratories implicated and/or WADA for guidance.

following steps with its quality the Samples in the Laboratory's custody, unless otherwise instructed by WADA:

- Samples which have 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 had been placed in long-term storage upon request by the Testing Authority or WADA:

These Samples shall be kept in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions. The Laboratory shall inform WADA of such actions including the provision of the Sample codes and the identity of the relevant Testing Authority(-ies).

If the Suspension has been 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 Testing Authority and WADA. In such cases, both the "A" and "B" containers of the relevant Samples shall be transferred ¹⁸ to another Laboratory(-ies) for Further Analysis, as determined by WADA. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the requested Analytical Testing menu or be limited to the class of Prohibited Substances and/or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by WADA.

- Samples for which Initial Testing Procedures had been completed, but results had not been reported at the time of the Suspension:

If the Initial Testing Procedure(s) have produced Presumptive Adverse Analytical Finding(s), both the "A" and "B" Samples shall be transferred ¹⁸ to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.

In addition, if the Suspension has been caused by the reporting of False Negative Finding(s) and the Initial Testing Procedure(s) have produced negative results, both the "A" and "B" Samples shall also be transferred ¹⁸ to another Laboratory(-ies) for the repetition of the Initial Testing Procedure(s) and, if needed, the performance of Confirmation Procedures. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the requested Analytical Testing menu or be limited to the class of Prohibited Substances and/or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding, as determined by WADA.

If the reason for the Suspension was not related to the reporting of False Negative Findings and the Initial Testing Procedures have produced negative results, the Sample(s) shall be reported in ADAMS 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 WADA. The Laboratory shall inform WADA of such actions including the provision of the Sample codes and the identity of the relevant Testing Authority(-ies).

- Samples which have been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Suspension:

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 into ADAMS and these Samples shall be kept in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until further notice by WADA. The Laboratory shall inform WADA of such actions including the provision of the Sample codes and the identity of the relevant Testing Authority(-ies).

However, if the Initial Testing Procedure has produced a Presumptive Adverse Analytical Finding, both the "A" and "B" Samples shall be transferred ¹⁸ to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.

If the Suspension has been caused by the reporting of False Negative Finding(s), then the Laboratory shall cease all Analytical Testing and have the "A" and "B" Samples transferred ¹⁸ to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.

- Samples which have been received at the Laboratory but not opened yet at the time of the Suspension:

These Samples shall be kept sealed in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until transfer ¹⁸ to another Laboratory(-ies) for Analytical Testing.

- 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 had been undergoing "A" or "B" Confirmation Procedures at the time of the Suspension:

Both the "A" and "B" Samples shall be transferred ¹⁸ to another Laboratory(-ies) for the repetition of the "A" and, if applicable, the "B" Confirmation Procedures.

- Samples which have been reported as an Adverse Analytical Finding based on the "A" Confirmation Procedure prior to the Suspension:

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 ¹⁸ to another Laboratory(-ies) for the "A" Confirmation Procedure to be performed again and for the performance of the "B" Confirmation Procedure, if applicable.

4.1.13.1.14.6.5.2.4 If the Suspension concerns the analysis of blood Samples for the ABP, Samples collected prior to the Suspension date may be analyzed by the Laboratory ¹⁹. The reporting of results for the relevant Sample(s) in ADAMS shall include a comment regarding the Suspension at the time of

¹⁹ Due to the negative impact of time on the integrity of blood Samples for the ABP analysis, it is not normally feasible to send the ABP blood Samples to other Laboratory(-ies) for timely analysis.

analysis so that the Testing Authority / APMU can take this information into account during the results management ~~system~~ process.

4.6.5.2.5 During a Suspension or Analytical Testing Restriction period, the Laboratory shall continue to participate in the WADA EQAS program. WADA may require the Laboratory to analyze additional blind EQAS samples and/or perform an on-site assessment, at any time and at the expense of the Laboratory, in order to evaluate the Laboratory's status.

4.6.5.3 Revocation

A laboratory whose WADA accreditation has been revoked is ineligible to perform ~~testing~~ Analytical Testing of ~~Doping Control~~ Samples for ~~Signatories~~ any Testing Authority. The ~~chain of custody~~ 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 WADA, for the transfer ¹⁸ of relevant Samples to ~~other Laboratories as soon as practical~~ a Laboratory(-ies).

~~If a~~ laboratory, whose WADA accreditation has been revoked, ~~should~~ shall arrange the transfer ¹⁸ of Samples in the laboratory's custody to a Laboratory(-ies) chosen by the Testing Authority or WADA, respectively, within thirty (30) calendar days of being notified of the decision revoking its WADA accreditation. In such circumstances, the Samples to be transferred shall be selected by the Testing Authority or WADA ²⁰. The laboratory transferring the Samples shall inform WADA and provide the relevant Sample codes and the identity of the relevant Testing Authority(-ies) and the chosen Laboratory(-ies). In addition, the revoked laboratory shall assist the relevant Testing Authority(-ies) with the transfer of the relevant Sample data and records to the Laboratory(-ies) that have been selected to receive the Samples.

4.6.6 Reinstatement of Suspended Accreditation or lifting of the Analytical Testing Restriction

WADA shall lift the Suspension of the Laboratory's WADA accreditation or lift the Analytical Testing Restriction only when the Laboratory provides satisfactory evidence, as determined by WADA, that appropriate steps have been taken to remedy the noncompliance(s) that resulted in the Suspension of the Laboratory's WADA 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 WADA accreditation.

²⁰ The 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 Testing Authority may also choose to transfer additional Samples retained in the laboratory in accordance with ISL Arts. 5.3.2.1. or 5.3.2.2., or other Samples for which it is the owner pursuant to Art. 10.1 of the ISTI and that have been analyzed and are in long-term storage at the time of the Revocation of the laboratory's WADA accreditation. In addition, WADA may identify and request that Samples be transferred to another Laboratory(-ies).

4.6.6.1 Extension of Suspension or Analytical Testing Restriction

If a Laboratory whose WADA accreditation has been suspended or has been the subject of an Analytical Testing Restriction has not satisfactorily corrected the ISL and/or Technical Document(s) and/or Technical Letter(s) noncompliance(s) that resulted in the Suspension or Analytical Testing Restriction, or if WADA identifies any additional ISL and/or Technical Document(s) and/or Technical Letter(s) noncompliance(s) during an on-site assessment conducted during the initial Suspension or Analytical Testing Restriction period, either the Suspension of the Laboratory's WADA accreditation or Analytical Testing Restriction shall be further extended or the Laboratory's accreditation shall be revoked, as determined by WADA.

The Suspension or Analytical Testing Restriction period may be extended up to a maximum of an additional six (6) months, based on justifiable delays in submitting satisfactory corrective actions. The Suspension of a Laboratory's WADA accreditation or the Analytical Testing Restriction, including any extensions of a Suspension or Analytical Testing Restriction, shall not exceed twelve (12) months, unless otherwise determined by WADA.

If applicable, a delay in the delivery of the ISO/IEC 17025 accreditation to the Laboratory by the relevant Accrediting Body may also constitute grounds to extend the Suspension of the Laboratory's WADA accreditation.

The decision to extend the Suspension of a Laboratory's WADA accreditation or the period of the Analytical Testing Restriction shall be rendered by the Chair of the WADA Executive Committee on the basis of a recommendation from the LabEG. WADA will provide the Laboratory with a decision of the Chair of the WADA Executive Committee extending the Suspension of the Laboratory's WADA accreditation or extending the period of the Analytical Testing Restriction.

The Laboratory may appeal WADA's decision to extend the Suspension of its WADA accreditation or to extend the period of the Analytical Testing Restriction in accordance with ISL Art. 4.6.4.7.

If, in accordance with the terms of the extension of the Suspension of the Laboratory's WADA accreditation or the terms of the extension of the Analytical Testing Restriction, the Laboratory provides evidence determined to be satisfactory by WADA that all of the identified ISL and/or Technical Document and/or Technical Letter noncompliance(s) have been corrected, the Laboratory's accreditation shall be re-instated or the Analytical Testing Restriction may be lifted by decision of the Chair of the WADA Executive Committee.

If the Laboratory has not provided evidence determined to be satisfactory by WADA at the end of the extended Suspension or extended Analytical Testing Restriction period, the Laboratory's accreditation shall be revoked. The decision to revoke a Laboratory's WADA accreditation shall be rendered by the WADA Executive Committee. WADA will notify the Laboratory of the decision of the WADA Executive Committee to revoke the Laboratory's WADA accreditation in accordance with ISL Art. 4.6.4.6.

The Laboratory may appeal WADA's decision to revoke its WADA accreditation in accordance with ISL Art. 4.6.4.7.

4.6.6.2 Revoked Accreditation

If a laboratory whose WADA accreditation has been revoked wishes to seek a new WADA accreditation, it shall begin the process must apply for WADA accreditation as a new laboratory as described in Section in accordance with ISL Art. 4.1. The laboratory may provide to WADA evidence

When seeking a new WADA accreditation, the laboratory may request that WADA expedite the laboratory re-accreditation procedure, which supports shall be approved by the WADA Executive Committee. To do so the laboratory shall provide WADA, as part of its application for a new accreditation, information that it considers constitutes "exceptional circumstances" that may justify adjustment to as justification for modifying the requirements in section of ISL Arts. 4.1. If such justification is accepted, as determined solely by the WADA Executive Committee, then the WADA Executive Committee shall to 4.3 to expedite the entry of the laboratory into, and/or shortening the duration of, the probationary phase of accreditation. At its sole discretion, WADA's Executive Committee may determine what steps shall whether such modifications are justified, and which steps must be followed prior to granting a new approval to the laboratory to enter the probationary phase of accreditation.

4.4.13.3 Evaluation of accreditation status

Upon receipt of all documentation required to investigate the issue(s) for Suspension or Revocation, WADA shall review the submission and present a written report, which may include recommendation(s), to the Disciplinary Committee.

Subsequently the Disciplinary Committee, as set up under WADA procedural rules, shall make an independent recommendation to the Chair of the WADA Executive Committee regarding the duration of Suspension or the Revocation of the WADA accreditation.

WADA shall lift the Suspension only once sufficient evidence, as determined by WADA, is provided by the Laboratory that appropriate steps have been taken to remedy the issue(s).

1.2.11 Notification

4.4.14.1 Written Notice

When a Laboratory is suspended or WADA seeks to revoke accreditation, WADA shall serve the Laboratory with written notice of the Suspension or proposed Revocation

by facsimile, hand delivery, or registered or certified mail, return receipt requested as soon as possible. This notice shall state the following:

- 1) The reason for Suspension or Revocation;
- 2) The terms of the Suspension or Revocation; and
- 3) The period of Suspension.

4.4.14.2 Effective Date and Appeals

A Suspension is immediately effective upon notification.

A Revocation takes effect 30 days after notification. A Laboratory which has received notice that its accreditation is in the process of being revoked shall be under Suspension until the Revocation is made final or is rescinded by WADA. If WADA decides not to uphold the Suspension or proposed Revocation, the Suspension is terminated immediately and any proposed Revocation shall not take place.

WADA's decision to suspend or revoke a Laboratory's accreditation may be appealed by the Laboratory to CAS within 21 days from the decision notification.

4.4.14.3 Public Notice

WADA shall immediately announce a Laboratory's accreditation status on the WADA website including the name and address of any Laboratory that has had its accreditation suspended or revoked, and the name of any Laboratory that has had its Suspension lifted.

~~WADA's website shall be updated regarding a Laboratory's accreditation status.~~

1.2.12 Re-accreditation costs

~~On an annual basis, WADA will invoice the Laboratory for a portion of the costs associated with the re-accreditation process. The Laboratory shall assume the travel and accommodation expenses of the WADA representative(s) in the event of on-site assessments.~~

1.2.13 Issuing and publication of accreditation certificate

If maintenance of accreditation is approved, the Laboratory shall receive a certificate signed by a duly authorized representative of WADA issued in recognition of such accreditation. Such a certificate shall specify the name of the Laboratory and the period for which the certificate shall be valid. Certificates may be issued after the effective date, with retroactive effect.

4.6.7 Voluntary Cessation of Laboratory Operations

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 ISL noncompliance(s) and not having been subject to an Analytical Testing Restriction or Suspension or Revocation of its WADA accreditation.

In such circumstances, the Laboratory shall inform WADA 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 ISL Arts. 4.6.5.2 (temporary closure) or 4.6.5.3 (permanent closure). In addition, if the Laboratory decides to cease its operations on a permanent basis, the Laboratory shall assist the relevant Testing Authority(-ies) with the transfer of relevant Sample data and records to the Laboratory(-ies) that have been selected to receive the Samples.

4.24.7 Accreditation ~~requirements~~ Requirements for Major Events

~~Primarily, Major Event Organizers~~ Organizations should ~~consider transporting Samples~~ give preference to ~~the use~~ existing facilities of ~~an accredited~~ a Laboratory for the analysis of Samples.

In some cases, the reporting time requirements for a Major Event may require that the Laboratory facility be located in proximity to the ~~Competition~~ Major Event such that Samples can be delivered by ~~Event~~ Doping Control staff. This may require ~~re-location of the establishment by~~ an existing Laboratory ~~for of~~ a ~~period of time~~ temporary "satellite facility", which shall start sufficiently in advance to validate operations at the "satellite facility" and perform the ~~testing~~ Analytical Testing for the Major Event.

In addition, the Laboratory ~~support~~ operations necessary for a Major Event may be such that the existing ~~accredited~~ Laboratory facilities are not adequate. This may require ~~the expansion of existing facilities~~, re-location of the Laboratory to a new permanent facility, the addition of personnel, and/or the acquisition of additional equipment. The ~~Laboratory~~ Director of the ~~WADA accredited laboratory~~ Laboratory designated to perform the ~~testing~~ Analytical Testing shall ~~be responsible to~~ ensure that a proper ~~quality management system~~ Management System, performance, security and safety are maintained.

~~In cases where Samples will be transferred to an existing Laboratory facility, there~~ There shall be agreement ~~sufficiently ahead of the Major Event~~ between the Major Event Organizer ~~Organization~~ and the ~~WADA accredited laboratory in regards to testing~~ Laboratory with respect to Analytical Testing requirements such as ~~test result turn-around time, the expected number of blood and urine Samples to be analyzed, or the number of specific analyses (i.e. not considered as part of the routine Analytical Testing menu) required.~~ The Laboratory shall be required to report on staffing and equipment issues as required by WADA.

~~If the Laboratory is required to move or extend its operation temporarily to a new physical location, the Laboratory shall demonstrate a valid ISO/IEC 17025 accreditation with primary compliance with the Application of ISO/IEC 17025 to the Analysis of Urine Doping Control Samples (Section 5.0) and if necessary, the Application of ISO/IEC 17025 to the Analysis of Blood Doping Control Samples (Section 6.0) for the new facility or "satellite facility".~~

~~All methods or equipment unique to the satellite facility shall be validated or qualified prior to the satellite facility accreditation assessment. Any changes to methods or other procedures in the quality manual shall also be validated prior to the assessment.~~

~~The Laboratory shall be responsible for providing WADA with regular and timely updates on the progress of the testing facilities.~~

4.2.14 Major Event testing in the Laboratory facilities

4.5.1.1 Participating in an initial WADA/Accreditation Body assessment

4.7.1 Major Event Analytical Testing in the Laboratory Facilities

When Analytical Testing services for a Major Event are provided in the existing facilities of a Laboratory, the WADA accreditation status of the Laboratory shall apply, and no additional WADA Accreditation Certificate for the Major Event needs to be issued. However, the Laboratory shall meet the requirements listed below in this ISL Arts. 4.7.1.1 to 4.7.1.3.

If requested by the Major Event Organization and in accordance with applicable national laws or workplace regulations, Laboratories providing Analytical Testing services during a Major Event or storing Samples collected at a Major Event should, when justified, monitor the Laboratory perimeter and the access to Sample storage room(s) (e.g. through the use of CCTV cameras).

4.7.1.1 Participation in WADA Assessment(s)

WADA may perform one or more on-site visit/assessment(s) to the Laboratory facility as soon as it is available to determine whether the facility is Fit-for-purpose/Purpose. Expenses related to such a visit shall be at the Laboratory's expense. Particular emphasis will be placed on the adequacy of security considerations, the physical layout of the space to ensure that adequate separation of various parts of the Laboratory are maintained, ~~and~~ to provide a preliminary review of other key support elements and to assess compliance with the ISL and Technical Documents and Technical Letters.

~~4.5.1.2~~ The Laboratory shall address and satisfactorily correct all noncompliances identified during the on-site assessment(s) or resulting from its analysis of EQAS samples. The documentation of the corrective actions shall be submitted to WADA as instructed and prior to start of the scheduled Analytical Testing for the Major Event.

4.7.1.2 Participation in the WADA EQAS

At its sole discretion, WADA may submit EQAS samples to the Laboratory for analysis.

The Laboratory shall implement, document, and provide to WADA corrective action(s) for failure to successfully complete the EQAS. Unsatisfactory responses and/or required action shall result in disqualification of the Laboratory from performing the Analytical Testing for the Major Event.

The EQAS process should include any additional personnel added to the staff for the Major Event. The EQAS samples shall be analyzed using the same Analytical Testing Procedures that will be used for the analysis of Samples for the Major Event.

~~4.2.1.14.7.1.3~~ Completing a Pre-Event Report on Facilities and Staff

~~4.7.1.3.1~~ The Laboratory shall ~~report to~~inform WADA of all senior personnel temporarily working in the Laboratory— for the Major Event.

~~4.2.1.14.7.1.3.2~~ The Laboratory Director shall ensure that these personnel are adequately trained in the methods, policies, and procedures of the Laboratory. Particular emphasis should be given to the

Code of Ethics and the confidentiality of the results management process. Adequate documentation of training of these temporary employees shall be maintained by the Laboratory.

4.2.1.1-24.7.1.3.3 At least two (2) months prior to start of ~~testing~~Analytical Testing for the Major Event, the Laboratory shall provide a report to WADA consisting of the following:

- A valid signed contract between the Laboratory and the responsible Testing Authority / Major Event organizerOrganization including a Test Distribution Plan detailing the Sample collection schedule ~~and~~, number of urine and blood Samples to be analyzed, and requests for specific analyses (e.g. agents affecting erythropoiesis);
- An organizational chart including Laboratory staff and temporary ~~staff~~ scientists employed by the Laboratory for the Major Event. Supporting information such as job titles and responsibilities shall be included;
- A training plan with timelines for new staff, including temporary staff and invited scientists;
- A list of instrumental resources and equipment including identification of ownership;
- A summary of the results management process including criteria for determining analytical results (Adverse Analytical Findings, Atypical Findings, etc.); and
 - ~~Method(s) of reporting the test results in a secure manner to the appropriate authorities.~~
- List of Analytical Testing Procedures within the Laboratory's Scope of ISO/IEC 17025 Accreditation and other method details as requested by WADA.

Any changes ~~that occur prior to~~ to the elements included in the start of Testing for the Major Event Laboratory report should be immediately reported to WADA.

4.7.1.3.4 EvenAdditional Professional Liability Insurance Coverage

Laboratories performing Analytical Testing during a Major Event shall verify their professional liability risk insurance coverage and, if the testing is appropriate, obtain complementary coverage to be done at adequately cover liability associated with the analysis of Samples and the Laboratory's existing facility, the Pre-Event Report shall be completed, particularly in regard to personnel changes and any hiring of additional equipment.

4.5.1.3 Reviewing the reports and correct identified non-conformities

The Laboratory shall address and correct all identified non-compliances. The assessment report and documentation of the corrective actions shall be submitted to WADA as instructed and prior to start of scheduled Testing for the Major Event.

~~4.5.1.4 External Quality Assessment Scheme~~

~~WADA may, at its sole discretion, submit EQAS samples to the Laboratory for analysis. The use of these EQAS samples may be part of the ISO/IEC 17025 assessment by the relevant accreditation body.~~

~~Failure to successfully complete the EQAS will be considered by WADA in deciding whether to accredit the Laboratory for the Major Event. In such event, the Laboratory shall implement, document, and provide to WADA proper corrective action(s).~~

~~The EQAS process should include any additional personnel that are added to the temporary staff for the Major Event. The EQAS samples shall be analyzed using the same methods and procedures that will be used for the analysis of Samples for the Major Event.~~

~~4.5.1.5 Reporting~~

~~All test result reporting shall be in accordance with the confidentiality requirements of the Code.~~

~~4.5.1.6 Monitoring and assessment during the Major Event~~

~~WADA may choose at its sole discretion to have an observer in the Laboratory during the Major Event. The Laboratory Director and staff are expected to provide full cooperation to the observer.~~

~~4.2.24.7.2 WADA, in conjunction with the Major Event Organization or relevant International Federation, may submit Double Blind EQAS samples to the Analytical Testing in "Satellite" Laboratory- Facilities~~

~~In the event of a false Adverse Analytical Finding, the Laboratory shall immediately cease testing for that class of Prohibited Substances and Prohibited Methods. The Laboratory shall apply corrective action(s) within 12 hours of notification of the false Adverse Analytical Finding. All Samples analyzed prior to the false Adverse Analytical Finding will be re-analyzed for the class of Prohibited Substances and Prohibited Methods for which the non-compliance occurred. The results of the investigation and analysis will be presented to WADA within 24 hours unless otherwise agreed in writing.~~

~~In the event of a false negative, the Laboratory will be required to investigate the root cause and apply corrective actions within 24 hours of notification of the false negative result. A representative group of Samples in appropriate number to ensure that the risk of false negatives is minimal will be re-analyzed for the class of~~

~~Prohibited Substances and Prohibited Methods~~ for which the non-compliance occurred. The results of the investigation and analysis will be presented to WADA within 48 hours unless otherwise agreed in writing.

~~1.2.15~~ Major Event testing in satellite Laboratory facilities

In addition to the accreditation requirements for Major Events, ~~satellite laboratories listed in ISL Art. 4.7.1 above, if the Laboratory is required to move or extend its operations temporarily to a new physical location ("satellite facility"), it~~ shall also meet the following requirements:

~~4.2.2.14.7.2.1~~ 4.5.2.1 Participating in an initial WADA / Accreditation Body assessments

WADA may perform ~~one or more an initial on-site visit(s)~~ assessment to the Laboratory "satellite facility" as soon as it is available to determine whether the facility is adequate. ~~Expenses~~ The Laboratory shall be responsible for expenses related to such ~~a visit on-site assessment(s) shall be at the Laboratory's expense.~~ It is a WADA requirement that an ISL trained assessor shall participate in the ~~accreditation body~~ Accreditation Body assessment of the "satellite facility." Particular emphasis will be placed on the adequacy of security considerations, the physical layout of the space to ensure that adequate separation of various parts of the Laboratory are maintained, and to provide a preliminary review of other key support elements and to assess compliance ~~to~~ with the ISL and ISO/IEC 17025.

~~4.7.2.2~~ 4.5.2.2 The Laboratory shall be responsible for providing WADA with regular and timely written updates on the progress of the testing facilities and capabilities.

~~4.7.2.3~~ All methods or equipment unique to the "satellite facility" shall be validated or qualified at least one (1) month prior to the "satellite facility's" final accreditation assessment by WADA. Any changes to Test Methods, equipment or other procedures in the Quality Manual shall also be validated prior to the assessment.

~~4.2.2.24.7.2.4~~ Documenting ISO/IEC 17025 accreditation Accreditation of the satellite facility Satellite Facility

At least one (1) month prior to the start of the scheduled Analytical Testing for the Major Event, the Laboratory must provide documentation that the relevant ~~accreditation body~~ Accreditation Body has ~~accredited the approved the continued accreditation or accepted the suitability of the~~ "satellite facility in compliance with the Application of ISO/IEC 17025 to the Analysis of Urine *Doping Control Samples* (Section 5.0) and the Application of ISO/IEC 17025 to the Analysis of Blood *Doping Control Samples* (Section 6.0), as applicable."

~~4.2.2.34.7.2.5~~ ~~4.5.2.3~~ Participating in WADA ~~accreditation—assessment~~ Accreditation Assessment(s)

WADA ~~may choose to~~ shall perform ~~an~~ on-site assessment (s) or ~~a~~ document ~~assessment~~ audit(s) of the “satellite facility”. ~~Should an on-site assessment take place, WADA expenses~~. Expenses related to ~~the assessment will~~ such visit(s) shall be at the Laboratory’s expense. ~~This~~ These assessment (s) may include analysis of a set of EQAS samples. Particular emphasis will be placed on involvement of new staff members to assess their competence.

~~4.5.2.4~~ ~~Issuing and publishing of a temporary and limited Accreditation certificate~~

4.7.2.6 Professional Liability Insurance Coverage

Before WADA grants accreditation for Analytical Testing during the Major Event, “satellite” laboratories shall provide documentation to WADA that professional liability risk insurance coverage has been obtained to cover liability associated with the analysis of Samples during the Major Event.

4.7.2.7 Obtaining a Temporary and Limited WADA Accreditation Certificate

The Laboratory’s “satellite facility” shall obtain a Temporary and Limited WADA Accreditation Certificate for the Major Event.

Based on the documentation provided, WADA reserves the right to make a decision regarding accreditation of the Laboratory ~~“satellite facility”~~. In the event that the accreditation is awarded, WADA shall issue ~~an accreditation~~ a Temporary and Limited WADA Accreditation Certificate for the period of the Major Event ~~and, which includes~~ an appropriate time before and after the ~~actual~~ duration of the Major Event.

In the event that the accreditation is not awarded, it is the responsibility of the Testing Authority / Major Event Organizer ~~Organization~~ to activate a contingency plan in order to ensure ~~analysis~~ Analytical Testing of Samples in compliance with ISL requirements during the Major Event.

4.7.3 Monitoring and Assessment during a Major Event

4.7.3.1 WADA may choose, at its sole discretion, to have one (1) or more observer(s) in the Laboratory during the Major Event. The Laboratory Director and staff shall provide full cooperation and access to the observer(s).

4.7.3.2 WADA, in conjunction with the *Major Event Organization* or relevant International Federation, may submit double-blind EQAS samples to the Laboratory.

4.7.3.3 In the event of a *False Adverse Analytical Finding*, the Laboratory shall immediately cease Analytical Testing for that class of *Prohibited Substances* or *Prohibited Methods*. The Laboratory shall apply corrective action(s) within twelve (12) hours of notification of the *False Adverse Analytical Finding*. All Samples analyzed prior to the reporting of the *False Adverse Analytical Finding* and reported with an *Adverse Analytical Finding* for the class of *Prohibited Substances* or *Prohibited Methods* for which the noncompliance occurred shall be re-analyzed. The results of the investigation and analysis shall be presented to WADA within twenty-four (24) hours unless otherwise agreed in writing.

4.7.3.4 In the event of a *False Negative Finding*, the Laboratory will be required to investigate the root cause and apply corrective actions within twenty-four (24) hours of notification of the *False Negative Finding*. An appropriate number of Samples reported as a *Negative Finding* for the class of *Prohibited Substances and Prohibited Methods* for which the noncompliance occurred shall be re-analyzed. The results of the investigation and analysis shall be presented to WADA within forty-eight (48) hours unless otherwise agreed in writing.

4.8 Process for approval of Laboratories for the ABP

The network of WADA-accredited laboratories may be geographically limited to fully serve the practical development of the ABP. Therefore, non-WADA-accredited laboratories, which have the capacity to analyze blood Markers, may apply for WADA approval for the purposes of conducting blood Samples analysis in support of the hematological module of the ABP in regions that cannot be served by a Laboratory. This section describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining WADA approval for the ABP.

4.8.1 Applicant Laboratory for WADA approval for the ABP

In principle, any laboratory that satisfies the criteria listed below may apply to become a candidate laboratory for WADA approval for the ABP. However, the WADA Executive Committee, in its sole discretion, may accept or deny a laboratory's candidacy application based on the identified needs (or lack thereof) for anti-doping Analytical Testing for the ABP on a regional or national scale, or for any other reason(s).

4.8.1.1 Expression of Interest

The applicant laboratory shall officially contact WADA in writing to express its interest in becoming a WADA-Approved Laboratory for the ABP.

4.8.1.2 Submit Initial Application Form

The applicant laboratory shall submit a completed initial application form, provided by WADA, with supporting documentation for review by the LabEG.

An applicant laboratory may only submit an application if its host country satisfies the following conditions:

- The existence of a National Anti-Doping Program conducted by a *National Anti-Doping Organization* and/or a *Regional Anti-Doping Organization* which is compliant with the *Code* and the *International Standards* of the World Anti-Doping Program;
- The ratification of the UNESCO Convention against Doping in Sport; and
- The payment of the annual financial contributions to WADA.

These conditions shall be documented as part of the application.

4.8.1.3 Provision of Letter(s) of Support

Upon receipt of an application and verification of the conditions mentioned above, WADA shall request that the applicant laboratory submit letter(s) of support from one or more *Code-compliant Anti-Doping Organization(s)*. The letter(s) of support shall indicate the estimated number of ABP blood Samples that will be provided per year to the applicant laboratory, as well as the reason(s) why an existing Laboratory or WADA-Approved Laboratory for the ABP is not a viable option for the *Anti-Doping Organization's ABP* program.

4.8.2 Candidate Laboratory for WADA approval for the ABP

The application materials described in ISL Arts. 4.8.1.1 to 4.8.1.3 shall be evaluated by the WADA Executive Committee to determine whether the applicant laboratory will be granted WADA candidate laboratory status for the ABP and thereby continue within the WADA approval process.

4.8.2.1 Description of the Candidate Laboratory

Once approved by the WADA Executive Committee, the candidate laboratory shall complete a detailed questionnaire provided by WADA and submit it to WADA within eight (8) weeks following receipt. The questionnaire will include, but is not limited to, the following:

- List of staff that will be responsible for the ABP analyses and their qualifications;
- Description of the physical laboratory facilities, including a description of the security considerations for Samples and records (see ISL Art. 5.2.3.4):
 - Physical Security: specific measures to maintain a secure laboratory environment (e.g., CCTV monitoring, restricted access to sample storage areas);
 - IT Security: implementation of firewalls and other current cyber security measures consistent with best practice and any applicable governmental regulations;
 - Information Technology (IT) infrastructure: implementation of a data and information management system (e.g. LIMS), central server/intranet which allows for secure data handling.
- List of actual and proposed instrumental resources and equipment for the ABP, including year of purchase and conditions for instrument technical support (access to manufacturer maintenance services);
- Status of the ABP method development and validation. Method validation report (if completed);
- Status of ISO/IEC 17025 ~~to the~~ or ISO 15189 accreditation;
- Description of customs regulations in the host country with respect to the reception of blood samples and consumables from abroad and the ability to ship blood Samples outside the country as needed; and
- Letter of compliance with the Code of Ethics (ISL Annex A) signed by the laboratory Director.

WADA may require an update of this documentation during the process of accreditation.

4.8.2.2 Laboratory Independence and Impartiality

In order to avoid potential conflicts of interest, the laboratory shall be administratively and operationally independent from any organization, which could exert undue pressure on the laboratory and affect the impartial execution of its tasks and operations. This applies to, but is not limited to, Anti-Doping Organizations or any other sport or political organizations.

- Administrative independence requires that the laboratory is a separate legal entity without any administrative links to an Anti-Doping Organization or other sport or political organizations;

- Operational independence requires that the laboratory shall manage its own affairs without hindrance, interference or direction from any *Anti-Doping Organization*, sport organizations or any *Person*.

4.8.2.3 Compliance with the Code of Ethics (ISL Annex A)

The candidate laboratory shall implement and comply with the provision(s) of the Code of Ethics. The laboratory shall provide the Code of Ethics to all employees responsible for the *ABP* analyses and ensure their understanding and compliance with all aspects of the Code of Ethics.

4.8.2.4 Obtaining ISO/IEC 17025 or ISO 15189 Accreditation

The applicant laboratory shall obtain ISO/IEC 17025 or ISO 15189 accreditation from an Accreditation Body, which is an ILAC full member and is a signatory to the ILAC MRA.

The laboratory shall correct and document any identified nonconformities with the ISO/IEC 17025 or ISO 15189 requirements within defined timelines. The Accreditation Body should send a summary of the Assessment Report and any corrective/preventive action documentation addressing identified nonconformities, in English or French, to WADA. Should the applicant laboratory prefer to send the information directly to WADA, the laboratory shall do so within a reasonable timeline.

A valid ISO/IEC 17025 or ISO 15189 accreditation certificate and Scope of Accreditation shall be provided to WADA before the WADA-approval can be granted.

4.8.2.5 WADA On-Site Assessment for the *ABP* Approval

Prior to approval, WADA shall conduct an on-site assessment of the candidate laboratory at the laboratory's expense. The purpose of this assessment is to obtain information about different aspects of the laboratory's competence and verify compliance with the relevant ISL and TD BAR (Technical Document on "Blood Analytical Requirements for the *Athlete Biological Passport*") requirements for the *ABP* and to clarify any issues with regard to the approval process.

WADA shall provide an Assessment Report regarding the outcomes of the on-site assessment, including any identified nonconformity(-ies), in order to allow the applicant laboratory to implement the necessary improvements. Corrective actions, if requested by WADA, shall be conducted and reported by the candidate laboratory to WADA within thirty (30) calendar days, or as otherwise indicated by WADA.

The nonconformities identified in the WADA Assessment Report shall be satisfactorily addressed and the recommendations for improvement should be implemented before the laboratory can be accepted as a WADA-Approved Laboratory for the *ABP*. The laboratory's performance in the on-site assessment will be taken into account in the overall review of the laboratory's status and may affect the timeliness of the WADA approval.

4.8.2.6 Participating in the WADA EQAS Program for the analysis of *ABP* blood Markers

The candidate laboratory shall be required to participate in at least three (3) WADA EQAS rounds for the analysis of ABP blood Markers with satisfactory performance, as determined by the LabEG. During this period, WADA may provide feedback to assist the laboratory to improve the quality of its Analytical Testing process.

4.8.2.7 Professional Liability Insurance Coverage

Before WADA grants approval, candidate laboratories shall provide documentation to WADA that professional liability risk insurance coverage has been obtained to cover liability of no less than two (2) million USD annually.

4.8.3 Granting of WADA Approval for the ABP

The maximum length of time during which a laboratory can remain as a candidate laboratory for the ABP is one (1) year, unless WADA determines that there are exceptional circumstances that justify an extension of this period.

Upon successful fulfilment of the requirements stated in the preceding provisions by a candidate laboratory, the LabEG will submit a recommendation to the WADA Executive Committee to grant the laboratory the status of WADA-Approved Laboratory for the ABP.

4.8.3.1 Issuing and Publishing of WADA Approval Certificate for the ABP

Upon granting of WADA approval for the ABP, a WADA Approval Certificate signed by a duly authorized representative of WADA (exclusive to Analytical Testing in support of the Hematological Module of the ABP) will be issued to the laboratory. The WADA Approval Certificate shall specify the name of the WADA-Approved Laboratory for the ABP and the period of validity. WADA Approval Certificates may be issued after the effective date of the WADA approval, with retroactive effect. A list of WADA-Approved Laboratories for the ABP shall be maintained on WADA's website and in ADAMS for stakeholder reference.

4.8.4 Maintaining Status as a WADA-approved Laboratory for the ABP

The laboratory shall meet the following requirements to maintain its WADA approval status for the ABP:

- Analysis of ~~Urine Doping-Control Samples~~ ABP blood Samples from Testing Authorities, which are Code-compliant Anti-Doping Organizations, as determined by WADA;
- Satisfactory performance, as determined by WADA, in a WADA EQAS or similar WADA-approved quality assurance program for the analysis of ABP blood Markers and during routine Analytical Testing of ABP blood Samples;
- Maintenance of a valid ISO accreditation (ISO/IEC 17025 or ISO 15189);
- Availability of analytical instrumentation, which is compliant with the requirements of the hematological module of the ABP, as determined by WADA;

- Implementation of Analytical Testing Procedures for the measurement of individual *Athlete* blood *Markers*, which are in compliance with the TD BAR;
- Compliance with relevant *WADA* documents, including the relevant articles of the ISL Section 5 relevant to the analysis of blood *Samples*;
- Documented compliance with the Code of Ethics (ISL Annex A);
- Maintenance of Professional Liability Insurance Coverage;
- Implementation of Laboratory Internal Chain of Custody procedures, which are compliant with the Technical Document on Laboratory Documentation Packages (TD LDOC);
- Production of Blood *ABP* Laboratory Documentation Packages or Blood *ABP* Laboratory Certificates of Analysis in compliance with the TD LDOC;
- Cooperation in support of the administrative and legal processes instigated when anti-doping rule violations are issued and managed by *Anti-Doping Organizations*.

4.8.4.1 A laboratory's *WADA* approval for the *ABP* may be suspended or revoked whenever the *WADA*-Approved Laboratory for the *ABP* fails to comply with the ISL and/or applicable Technical Document(s) and/or Technical Letter(s) , or where the Suspension or Revocation of the laboratory's approved status is otherwise required in order to protect the integrity of the *ABP* blood *Samples*, the Analytical Testing process for the *ABP* and the interests of the Anti-Doping Community.

Disciplinary proceedings to suspend or revoke a laboratory's *WADA* approval for the *ABP* shall be conducted in accordance with the procedures described in ISL Art. 4.6.4.5, and any references made therein, and the Procedural Rules found in Annex B of the ISL, all of which shall apply *mutatis mutandis*.

5.0 Application of ISO/IEC 17025 to the Analysis of Samples

5.1 Introduction and Scope

This section of the ~~document~~ISL is intended as an ~~application as described in Annex B.4 (Guidelines for establishing applications for specific fields)~~extension of the application of ISO/IEC 17025 to the field of *Doping Control*. Any aspect of ~~testing~~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 WADA-accredited laboratory (*i.e. a Laboratory*) or WADA-Approved Laboratory for the ABP and are therefore ~~determined to be~~ significant in the evaluation and accreditation process.

This section introduces the specific performance standards for a Laboratory or WADA-accredited laboratory-Approved Laboratory for the ABP, as applicable. The conduct of ~~testing~~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:

- Structural and Resource Requirements;
- Process Requirements;
- Management Requirements.

5.2 Structural and Resource Requirements

5.2.1 General

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

5.2.2 Laboratory Personnel

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

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

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

5.2.2.4 Laboratory Director

The Laboratory shall have a qualified *Person* as the Laboratory Director to assume professional, organizational, educational, operational and administrative responsibilities. The Laboratory Director plays an essential role in the anti-doping Laboratory's operations and the WADA accreditation is delivered based upon such qualification as well as on the Laboratory's operational performance.

The Laboratory Director qualifications shall include:

- Doctoral degree (Ph.D. or equivalent) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area. In the absence of a Doctoral degree, at least a Master's degree and extensive and appropriate anti-doping science experience and training (e.g. a senior Laboratory position for a minimum of ten (10) years), including the documented ability to develop analytical methodology and oversee research projects;
- Experience and competence in the analysis of chemical and biological material for the classes of substances and methods used in doping;
- Knowledge of drug metabolism and pharmacokinetics;
- Proficiency in English to an extent that allows adequate performance of functions as part of the international anti-doping community and in accordance with the Code, the ISL, Technical Documents, Technical Letters and Laboratory Guidelines.

Any personnel changes to the position of Laboratory Director shall be communicated to WADA no later than one (1) month prior to the scheduled date the Laboratory Director vacates his/her position. A succession plan shall be forwarded to WADA.~~• Analytical and technical processes;~~

~~• Management processes;~~

- ~~•~~ Support WADA reserves the right to review the credentials of such appointment and either approve it or reject it in accordance with the above qualifications.

5.2.2.5 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 should remain independent, as much as possible, from routine Laboratory analytical activities.

The Laboratory Quality Manager qualifications shall include:

- At least Bachelor's Degree (or similar) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical sciences;
- Appropriate experience of two (2) years or more in laboratory analytical procedures;
- Appropriate documented qualifications and training in laboratory quality management, including ISO/IEC 17025;
- Ability to ensure compliance with the Management System and quality assurance processes.

5.2.2.6 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.

The qualifications of Certifying Scientists shall include:

- At least a Bachelor's Degree (or similar) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area. In the absence of a bachelor's degree, documented experience of five (5) years or more in a Laboratory as senior scientist (e.g. supervisor, section head) may be considered equivalent to a Bachelor's degree for this position;
- Appropriate training and experience of three (3) years or more, as well as theoretical knowledge and technical competence in the analysis and interpretation of results for chemical or biological materials, including the classes of substances and methods used in doping;
- Knowledge of relevant WADA Technical Documents, Technical Letters, Laboratory Guidelines and other technical standards;
- Experience in the use of relevant analytical techniques such as chromatography, immunoassays, electrophoresis or mass spectrometry;
- Adequate training in the Laboratory's Management System and thorough understanding of its application into Laboratory processes.

5.2.2.7 Laboratory Supervisory Personnel

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.

The qualifications for a Laboratory Supervisor shall include:

- At least a Bachelor's Degree (or similar) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area. Documented experience of two (2) years or more in a Laboratory may be considered equivalent to a Bachelor's degree for this position;
- Experience in the use of relevant analytical techniques such as chromatography, immunoassays, electrophoresis or mass spectrometry;
- Ability to comply with the Management System and quality assurance processes.

5.2.3 Laboratory facility and Environmental Conditions

5.2.3.1 Environmental Control

5.2.3.1.1 Maintaining Appropriate Electrical Services

- The Laboratory shall ensure that adequate electrical service is available for scientific instrumentation by provision of an alternative power supply (e.g. UPS system and/or power generators).
- All Laboratory instrumentation and equipment critical to Laboratory operations should be supported in such a way that service is not likely to be interrupted.
- The Laboratory shall have policies in place to ensure the integrity of refrigerated and/or frozen stored Samples in the event of an electrical failure.

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

5.2.3.1.3 ~~Wherever possible, the application will follow the format~~The storage and handling of controlled substances shall comply with applicable national legislation.

5.2.3.2 Security of the ~~ISO/IEC 17025~~ document. The concepts of Facility, Equipment and Systems

The Laboratory shall have Fit-for-Purpose facilities including sufficient space for dedicated administrative, Sample handling, Sample storage and analytical areas, which comply with the security requirements outlined below.

5.2.3.2.1 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.

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

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

- 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.

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

Access to the Laboratory Controlled Zones shall be monitored and restricted to Laboratory staff and temporarily approved/authorized personnel (e.g. maintenance engineers, auditing teams). All other

visitors to the Laboratory Controlled Zones shall be continuously escorted by Laboratory staff member(s). Access to the Laboratory Controlled Zones shall be defined in the Laboratory's Management System.

5.2.3.2.4 The Laboratory should have a dedicated area within the Controlled Zone for *Sample* receipt and Aliquot preparation.

5.2.3.2.5 The Laboratory should have a dedicated area within the Controlled Zone for *Sample* storage.

5.2.3.2.6 Access to stored *Samples* ²¹ shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.

5.2.3.2.7 The Laboratory may implement additional security measures, which should be assessed on a case-by-case basis.

5.2.3.3 Confidentiality of data, information and operations

- The Laboratory should implement a clean desk policy and either file securely any confidential or sensitive information or properly destroy it before disposal. Laboratory staff shall be trained on how to comply with a clean desk policy, on how to ensure confidentiality of information and operations, as well as on the risks of corruption attempts by third parties.
- Laboratory staff shall be trained to protect their personal access badge during and out of working hours.
- In order to minimize any attempts of fraud or counterfeit, the Laboratory should implement a policy to ensure that discarded urine and blood *Sample* containers, as well as the seals and rings, cannot be collected by unauthorized staff or recovered after disposal (for example, bottles should be destroyed, or trash containers should be properly sealed).

5.2.3.4 Control of Data and Computer Security

5.2.3.4.1 All reasonable measures, including a thorough risk assessment and vulnerability test, shall be undertaken to prevent intrusion and copying of data from computer systems and to detect security failures. Laboratories shall implement firewalls and other cyber security measures consistent with best practice and any applicable governmental regulations.

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

~~5.1.1.1.15~~ 5.2.3.4.3 The Laboratory shall implement a data and information management system, continuous improvement, and customer satisfaction have been included. a software-based solution that supports and maintains proper traceability of Laboratory operations (e.g. a Laboratory

²¹ 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.

Information Management System, LIMS) with secure and restricted access to stored electronic data as well as information and data exchange capabilities (e.g. with Laboratory instruments and ADAMS). The system may also feature workflow management, data tracking support, Sample and Aliquot Laboratory Internal Chain of Custody, control of stocks of Reference Materials, etc., which can also be addressed with proper documentation.

5.2.3.4.4 The Laboratory shall implement a secure datafile storage system that prevents data loss (e.g. failed hard drive), unauthorized access and destruction of data (e.g. fire, flooding). The datafile storage system shall ensure that at least two (2) independent, regularly backed-up copies of all analytical/LIMS/instrument software files are available. At least one (1) backup copy shall be stored in a restricted and secure environment either in the Laboratory (e.g. fire and water-proof safe) or in a secure off-site location (e.g. in a mirrored server located in a restricted area that guarantees the integrity of the server and the stored data).

5.2.3.4.5 The software shall prevent the changing of results, unless there is a system to record the change and the Person doing the editing, and that editing is limited to users with proper level of access.

5.2.3.4.6 All data entry related to the reporting of test results, recording of reporting processes and all changes to reported data shall be recorded with an audit trail. This shall include the date and time, retention of original data, reason for the change to original data and the individual performing the task.

5.2.3.5 Laboratory Equipment

5.2.3.5.1 A list of available equipment shall be established and maintained.

5.2.3.5.2 As part of the Management System, the Laboratory shall operate a program for the maintenance and calibration of equipment according to ISO/IEC 17025.

5.2.3.5.3 General Laboratory equipment (fume hoods, centrifuges, evaporators, etc.) that is not used for analytical measurements should be maintained by visual examination, safety checks, performance verification and cleaning as necessary. Calibrations are only required where the setting can significantly 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).

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

5.2.3.5.5 Qualified vendors may be contracted to service, maintain, and repair equipment.

5.2.3.5.6 All maintenance, service, and repair of equipment shall be recorded.

5.2.3.6 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 WADA no later than three (3) months prior to the relocation:

- Description of the circumstances for moving Laboratory operations into a new space and anticipated effect on capabilities;
- Relocation date(s) including date of closing of existing facility operations and date of opening of future facility operations;

4.3 Analytical and Technical Processes

- ReceiptExpected date(s) of assessment of the new facilities by the Accreditation Body (evidence of continued accreditation and/or acceptance of suitability of the new Laboratory facility required when made available by the Accreditation Body);
- New Laboratory contact information and coordinates;
- Assessment of the effect of the Laboratory relocation on client operations.

5.3 Process Requirements

The Laboratory shall maintain paper or electronic Laboratory Internal Chain of Custody in compliance with the WADA Technical Document on Laboratory Internal Chain of Custody (TD LCOC).

~~5.1.2.5.3.1~~ Reception, Registration and Handling of Samples

~~5.1.2.45.3.1.1~~ ~~5.2.1.1~~ ~~Samples may be received by any method acceptable under the concepts of the~~ The Laboratory may receive Samples, which have been collected, sealed and transported to the Laboratory according to the WADA's International Standard for Testing and Investigations—(ISTI).

~~5.1.2.25.3.1.2~~ ~~5.2.1.2~~ ~~The transport container shall first be inspected, and any irregularities recorded.~~

~~5.1.2.35.3.1.3~~ ~~5.2.1.3~~ ~~The transfer of the Samples from the courier or other person delivering the Samples~~ delivery Person shall be documentedrecorded including, at a minimum, the date, the time of receipt, and the name and initials or (electronic) signature of the Laboratory representative receiving the Samples, and the courier company tracking number, if available. This information shall be included into the Laboratory Internal Chain of Custody record(s) of the Sample(s).

~~1.3.1~~ Handling and retention of Samples

~~5.1.2.45.3.1.4~~ The Laboratory shall have a system to uniquely identify the Samples and associate each Sample with the collection document or other external chain of custody information.

~~1.3.1.1~~ The Laboratory shall have Laboratory Internal Chain of Custody procedures to maintain control of and accountability for Samples from receipt through final disposition of the Samples. The procedures shall incorporate the concepts presented in the applicable WADA Technical Document for Laboratory Internal Chain of Custody.

5.3.1.5 ~~The Laboratory shall~~ Samples with irregularities

5.3.1.5.1 With the exception of the situation when a large number of *Samples* are received for long-term storage only (e.g. from a *Major Event Organizer*), as described in ISL Art. 5.3.2.3, the Laboratory ~~shall~~ observe and document conditions that exist at the time of ~~receipt~~ Sample reception or registration that may adversely impact on the integrity of a *Sample*. ~~For example, irregularities or on the performance of Analytical Testing Procedures. Only unusual conditions shall be recorded.~~

Irregularities to be noted by the Laboratory ~~should~~ may include, but are not limited to:

- ~~Sample~~ Sample transport conditions (e.g. delivery time, temperature), which may impact the integrity of the Sample for Analytical Testing, as determined by the Laboratory;
- Sample collection information (including Sample identification code), which is necessary to conduct the requested test menu, is not provided, e.g. missing or incomplete Doping Control Form (DCF);
- Sample identification is questionable. For example, the number on the Sample container does not match the Sample identification number on the DCF;
- Athlete information is visible on the Laboratory copy of the DCF or any other document transferred to the Laboratory;
- Sample identification numbers are different between the "A" and the "B" Sample containers of the same Sample;
- Tampering or adulteration of the Sample is evident;
- Sample is not sealed with tamper-resistant ~~evident~~ device or not sealed upon receipt;
 - ~~Sample is without a collection form (including Sample identification code) or a blank form is received with the Sample;~~
 - ~~Sample identification is unacceptable. For example, the number on the bottle does not match the Sample identification number on the form;~~
- Sample volume ~~is does not meet the Suitable Volume of Urine for Analysis or is otherwise inadequate to perform the requested~~ Analytical Testing ~~menu;~~
- Sample transport conditions are not consistent with preserving the integrity of the Sample for anti-doping analysis;
- The Sample condition(s) is unusual – for example: color, odor, presence of turbidity or foam in a urine Sample; color, haemolysis, freezing or clotting of a blood Sample; unusual differences in Sample appearance (e.g. color and/or turbidity) between the "A" and the "B" Samples ²².

5.3.1.5.2 ~~The Laboratory shall~~ notify and analyze each Sample received, unless the Sample meets any of the following:

²² Further guidance on assessing the differences between "A" and "B" *Samples* is provided in a Technical Letter.

- Criteria described in ISL Arts. 5.3.1.7 or 5.3.1.8; or
- Documented *Sample* rejection criteria, which have been agreed with the Testing Authority.

If justified by the irregularities observed, the Laboratory shall seek instructions from the Testing Authority regarding rejection or testing of *Samples* for which irregularities are noted. If on the performance of Analytical Testing on the *Sample*. The Testing Authority shall inform the Laboratory in writing within seven (7) calendar days whether a *Sample* with noted irregularities should be analyzed or not, and/or of any further measures to be taken (e.g. splitting the *Sample* in accordance with ISL Art. 5.3.1.6, forensic analysis, DNA analysis), or that the *Sample* should be stored for Further Analysis. The communication between the Laboratory and the Testing Authority shall be recorded as part of the *Sample's* documentation.

5.3.1.5.3 Each *Sample* not subject to analysis shall be reported as "Not Analyzed" in ADAMS, and the reason(s) for not analyzing the *Sample*, as instructed by or agreed with the Testing Authority, shall be specified (e.g. intermediate *Samples* of a Sample Collection Session, *Samples* with documented irregularities).

5.3.1.5.4 When an analysis on a *Sample* with documented irregularities is performed, the Laboratory shall record the irregularities noted in ADAMS.

5.3.1.5.5 The Results Management Authority shall determine the validity of Laboratory analytical results for a *Sample* with irregularities during the results management process.

5.3.1.6 *Sample* Splitting Procedure

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 and is leaking or has been broken; the *Sample's* integrity has been compromised in any way; the *Sample* is heavily contaminated), the Laboratory, in consultation with the Testing Authority, should consider splitting the other *Sample* container ("A" or "B", as applicable, any agreement between a Testing Authority and Laboratory that establishes *Sample* rejection criteria shall be documented-), provided that it is properly sealed. This process may be applied repeatedly, if necessary.

The first fraction of the split *Sample* shall be considered as the "A" *Sample* and shall be used for the Initial Testing Procedure(s), unless the Initial Testing Procedure(s) have already been performed, and the "A" Confirmation Procedure(s), if necessary. The second fraction, considered as the "B" *Sample*, shall be resealed and stored frozen for "B" *Sample* Confirmation Procedure(s), if necessary.

The process of opening and splitting the *Sample* and resealing of the remaining second fraction shall be conducted in accordance with ISL Arts. 5.3.4.5.4.8.6 and 5.3.4.5.4.8.9 as for a customary "B" *Sample* opening, including an attempt to notify the *Athlete* that the opening of the *Sample* to be split will occur on a specified date and time and advising the *Athlete* of the opportunity to observe the process in person

and/or through a representative ²³. When the *Athlete* and/or his/her representative does not attend the opening and splitting of the *Sample*, the procedure shall be done in the presence of an Independent Witness that is assigned by the Laboratory.

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. 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.

5.3.1.7 In cases where the Laboratory receives ~~more than two (2) urine~~ *Samples*, which are linked to a single ~~Sample collection session~~ *Collection Session* from the same *Athlete* according to the ~~Doping control form~~ *DCF(s)*, the Laboratory ~~should~~ *shall* analyze both *Samples* collected, unless otherwise instructed by the Testing Authority.

The Laboratory may combine Aliquots from the two (2) *Samples*, if necessary, in order to have sufficient volume to perform the required Analytical Testing Procedure(s).

~~5.1.2.55.3.1.8~~ In cases where the Laboratory receives three (3) or more urine *Samples*, which are linked to a single *Sample Collection Session* from the same *Athlete* according to the *DCF(s)*, the Laboratory shall prioritize the analysis of the first and ~~last~~ *Samples* collected; the subsequent collected *Sample* with the highest Specific Gravity (SG), as recorded on the *DCF*:

- The Laboratory may conduct further analyses on the ~~intermediary~~ *Samples* ~~additional~~ collected *Samples*, if deemed necessary ~~in consultation~~, with the agreement of the Testing Authority;
- The Laboratory may combine Aliquots from multiple *Samples*, ~~which are linked to a single Athlete according to the Doping Control form(s)~~, if necessary to conduct a proper analysis; if necessary, in order to have sufficient volume to perform the required Analytical Testing Procedure(s);
- With the agreement of the Testing Authority, the Laboratory may store the additional collected, non-analyzed *Samples* for Further Analysis;
- *Samples* not subject to analysis shall be reported as "Not Analyzed" in ADAMS, and the reason(s) for not analyzing the *Sample* shall be specified (e.g. additional *Sample* from a single *Sample Collection Session*).

²³ If the *Athlete* chooses to witness the *Sample* splitting procedure, the *Athlete* forfeits his/her anonymity.

5.3.2 Storage of Samples²⁴

5.3.2.1 Storage of Urine Samples

5.3.2.1.1 In order to maintain the stability and integrity of the urine Samples, the Laboratory shall implement Sample storage procedures that minimize time of storage at room and refrigerated temperatures as well as Sample freeze/thaw cycles.

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

5.3.2.1.3 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.

5.3.2.1.4 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 ("A" result in ADAMS, or for a maximum of ten (10) years after the Sample) report is transmitted to the collection date, if the long-term storage of the Sample(s) has been requested, in writing, by the relevant Testing Authority. The Sample(s) shall be stored frozen, or WADA²⁵.

5.3.2.1.5 Urine Samples with Irregularities

The Laboratory shall retain the "A" and "B" urine Sample(s) with irregularities shall be stored frozen for a minimum of three (3) months following the report to the after reporting in ADAMS, or for a longer period as determined by the Testing Authority, Results Management Authority or WADA²⁵.

5.3.2.1.6 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"

²⁴ 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.

²⁵ The Laboratory may charge storage costs to the Testing Authority or WADA, as applicable, for the storage of Samples for periods longer than the stated minimum storage times.

Sample, as applicable) in ADAMS ²⁶, or for a longer period as informed to the Laboratory, in writing, by the relevant Testing Authority, Results Management Authority or WADA ²⁵.

5.3.2.1.7 Urine Samples under challenge, dispute or investigation

If the Laboratory has been informed by the Testing Authority, the Results Management Authority or WADA (in writing and within the applicable storage period as defined in ISL Arts. 5.3.2.1.4 to 5.3.2.1.6) 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 Testing Authority, the Results Management Authority or WADA, as applicable ²⁵.

5.3.2.2 Storage of Blood Samples

5.3.2.2.1 Samples for which Analytical Testing will be performed on blood serum/plasma fraction only (not on cellular components):

The Laboratory shall follow the applicable Technical Document(s), Technical Letter(s) or Laboratory Guidelines for the obtaining and storage of Sample serum or plasma fractions.

Blood Samples ("A" and "B" Samples) should be centrifuged as soon as practical after Laboratory reception to obtain the serum or plasma fraction ²⁷.

The "A" Sample serum or plasma fraction (contained in the "A" Sample collection tube) and/or the "A" Sample serum or plasma Aliquots may be stored refrigerated for a maximum of 24 hours (but not surpassing the maximum allowed time from Sample collection established in the applicable Technical Document, Technical Letter or Laboratory Guidelines) or frozen until analysis. In all circumstances, the Laboratory shall take the appropriate steps to maintain the integrity of the Sample.

"A" Sample serum or plasma Aliquots used for "A" Confirmation Procedures shall be analyzed as soon as possible after thawing.

The "B" Sample serum or plasma fractions shall be immediately stored frozen in the "B" Sample collection tube according to established protocols until analysis, if applicable ²⁷.

All serum or plasma Samples retained for storage in the Laboratory shall be stored frozen according to established protocols in a secure location under continuous chain of custody. The Laboratory shall keep

²⁶ If the "B" Sample Confirmation Procedure is not performed, the Laboratory may dispose of both the "A" and "B" Samples within six (6) 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" urine Sample(s) for a minimum of six (6) months after reporting the "B" Sample analytical result.

²⁷ Unless otherwise specified in a WADA Technical Document, Technical Letter or Laboratory Guidelines.

all chain of custody and other records (either as hard-copy or in digital format) pertaining to those Samples.

5.3.2.2.1.1 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 in ADAMS, or for a maximum of ten (10) years after the Sample collection date, if the long-term storage of the Sample(s) has been requested by the relevant Testing Authority or WADA²⁵.

5.3.2.2.1.2 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 in ADAMS, or for a longer period as determined by the Testing Authority, Results Management Authority or WADA²⁵.

5.3.2.2.1.3 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) in ADAMS²⁶ or for a longer period as informed to the Laboratory, in writing, by the relevant Testing Authority, Results Management Authority or WADA²⁵.

5.3.2.2.1.4 Plasma/serum “A” and “B” Sample(s) under challenge, dispute or investigation

If the Laboratory has been informed by the Testing Authority, the Results Management Authority or WADA (in writing and within the applicable storage period as defined in ISL Arts. 5.3.2.2.1.1 to 5.3.2.2.1.3) 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 Testing Authority the Results Management Authority or WADA, as applicable²⁵.

5.3.2.2.2 Samples for which Analytical Testing will be performed on cellular fractions of whole blood

Whole blood Samples shall be maintained refrigerated and shall be analyzed according to established protocols. After Aliquots have been taken for analysis (if applicable), Samples shall be returned to refrigerated storage. Whole blood Samples shall not be frozen. In all circumstances, appropriate steps to ensure the integrity of the Sample(s) shall be taken by the Laboratory.

The Laboratory shall retain the whole blood Samples without an Adverse Analytical Finding or Atypical Finding stored refrigerated in a secure location under continuous chain of custody for a minimum of one (1) month after reporting the final analytical result in ADAMS.

If, after completion of analyses on the cellular components of whole blood, the *Sample* is centrifuged to obtain the plasma fraction for additional analyses (e.g. Agents Affecting Erythropoiesis), then the plasma *Sample* shall be stored according to ISL Art. 5.3.2.2.1.

5.3.2.3 Long-term Storage of *Samples*

5.3.2.3.1 At the direction of the Testing Authority or WADA, any urine or serum/plasma *Sample* may be stored in long-term storage for up to ten (10) years after the *Sample* collection date. The Laboratory shall ensure that *Samples* are stored according to established protocols in a secure location under continuous chain of custody. The written request from the Testing Authority or WADA for long-term storage of *Samples* shall be properly documented.

5.3.2.3.2 The Testing Authority shall retain the *Sample* collection records pertaining to all stored *Samples* for the duration of *Sample* storage.

5.3.2.3.3 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 Substances(s)* or *Marker(s)* of *Prohibited Substances(s)* or *Prohibited Method(s)* (e.g. full-scan mass spectrometry data) as provided for in ISL Art. 5.3.4.5.5.9.

5.3.2.3.4 *Samples* may be transported for long-term storage to a specialized, secure *Sample* storage facility, which is located outside the Laboratory's permanent controlled zone, or 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 have its own ISO accreditation or accredited certification (e.g. 17025, 20387, 9001). The transfer of the *Samples* to the long-term storage facility or Laboratory shall be recorded.

5.3.2.3.5 If *Samples* are transported to another Laboratory for long-term storage, the existing *Sample's* external chain of custody and other non-analytical records (e.g. DCF), available to the transferring Laboratory, shall also be transferred, immediately or upon later request, to the Laboratory storing the *Samples* or to the Testing Authority, either as originals or copies.

5.3.2.3.6 *Samples* transferred for long-term storage purposes are not subject to individual inspection by the receiving Laboratory until a *Sample* has been selected for Further Analysis.

5.3.2.3.7 If *Samples* are to be stored at a location outside the secured area of the Laboratory which first analyzed the *Samples*, the Laboratory shall secure the "A" *Samples* to be shipped either by re-sealing individual "A" *Sample* containers with a tamper-evident sealing system, which has similar capabilities for

security and integrity as the original sealing system ²⁸, or by sealing the box in which the *Samples* are shipped in a manner that maintains *Sample* integrity and chain of custody. Neither the *Athlete* nor his or her representative nor an Independent Witness is required to be present for this procedure.

"B" *Samples* to be shipped shall be individually sealed, either in the original, sealed "B" *Sample* container or, if previously opened, by re-sealing the individual "B" *Sample* container with a tamper-evident sealing system, which has similar capabilities for security, and integrity as the original sealing system ²⁸. The resealing of the "B" *Sample*, if necessary, shall be witnessed by either the *Athlete* or his/her representative or by an appointed Independent Witness (see ISL Art. 5.3.4.5.4.8.9 below).

5.3.2.3.8 During transport and long-term storage, *Samples* shall be stored at a temperature appropriate to maintain the integrity of the *Samples*. 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.

5.3.2.3.9 The long-term storage facility shall maintain security requirements comparable to the security requirements applicable to a Laboratory's short-term storage of *Samples*.

5.3.3 ~~After the applicable storage period above~~ Use, Transfer or Disposal of *Samples*

~~5.1.2.65~~ 5.3.3.1 When the minimum applicable *Sample* storage period has expired, and neither the Testing Authority, the Results Management Authority nor WADA have requested the long-term storage of the *Sample* for the purpose of Further Analysis or have informed the Laboratory that a challenge, dispute, or longitudinal study is pending, the Laboratory shall do one of the following with the *Sample(s)*:

- ~~Disposal~~ Dispose of the *Sample(s)* ²⁹.
 - If the ~~Testing Authority~~ has arranged for storage of the *Samples* for a period from three months to ~~ten~~ years, the ~~Laboratory~~ shall ensure that the *Samples* are stored in a secure location under continuous chain of custody;
- If consent has been obtained from the *Athlete*, retain the *Samples* ~~may be retained by the Laboratory~~ for research purposes. *Samples* used for research purposes shall have any means of identification removed or the *Sample* shall be transferred into an anonymous container such that the contents cannot be traced back to a particular *Athlete*. Research *Samples* may be transferred to other Laboratories or third parties (e.g. other research groups);

²⁸ For example, *Samples* may be resealed with resealing systems (e.g. "green" caps) produced by the manufacturer of the appropriate *Sample* collection equipment. The resealing system of shipped "A" *Samples* shall be tamper-evident.

²⁹ Disposal and long-term storage of *Samples* shall be conducted and recorded under the Laboratory Internal Chain of Custody.

If consent has not been obtained from the *Athlete*, ~~and provided that~~ retain the ~~anonymized Samples are made anonymous, the Samples may be retained by the Laboratory~~ for quality assurance ~~and~~ quality improvement purposes, including but not limited to:

- ~~Improving of existing analytical methods;~~
- ~~Developing Test Methods, development or evaluating evaluation of new analytical methods;~~
- ~~Developing reference ranges or Decision Limits or other statistical purposes;~~

~~Disposal and long-term storage of Samples shall be conducted and recorded under the Laboratory Internal Chain of Custody.~~

- ~~The Laboratory shall retain frozen the "A" and "B" Sample(s) with an Adverse Analytical Finding or Atypical Finding, and all chain of custody and other records pertaining to these Samples, for a minimum of three months after the final analytical report is submitted to the Testing Authority or as determined by the relevant Testing Authority and/or Results Management Authority 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, which are not considered as research. As such, these Samples may be used by the Laboratory or transferred to other Laboratories or to third parties for these purposes.~~

~~1.3.1.2 If the Laboratory has been informed by the Testing Authority that the analysis of a Sample is challenged, disputed or under longitudinal investigation, the Sample shall be stored frozen and all records pertaining to the Testing of that Sample shall be stored until completion of any challenge or investigation.~~

~~5.1.2.75.3.3.2~~ The Laboratory shall maintain a ~~policy~~ SOP(s) pertaining to ~~the~~ retention, ~~release,~~ use for research or quality assurance, transfer and disposal of Samples and Aliquots.

5.3.4 The Sample Analysis

5.3.4.1 Aliquoting for Analysis

~~1.3.1.3 It is recommended that the Laboratory shall maintain custody information on the transfer of Samples, or portions thereof assigns specific staff member(s) to another Laboratory.~~

~~1.3.1.4 In cases where both "A" Sample aliquoting, and "B" Samples have been reported with an Adverse Analytical Finding(s) and no challenge, dispute, or longitudinal study is pending, the Laboratory shall either make the Samples anonymous for research purposes (with proper consent from the Athlete) or dispose of the Samples. Samples~~

~~used for research purposes shall have any means of identification removed or be transferred into an anonymous container such that they cannot be traced back to a particular Athlete. Disposal of Samples shall be conducted and recorded under the Laboratory Internal Chain of Custody.~~

~~1.3.1.5 Long term storage of Samples~~

~~5.2.2.12.1 At the direction of the Testing Authority, any Sample may be stored in long term storage for up to ten years. Guidance on the that the process for long term storage of aliquoting is found in the document entitled Guidelines for Long Term Storage.~~

~~5.2.2.12.2 The Testing Authority should retain the Doping Control official records pertaining to all stored Samples for the duration of Sample storage.~~

~~5.2.2.12.3 The Laboratory should retain all chain of custody and other records pertaining to a stored Sample for the duration of Sample storage.~~

~~5.2.2.12.4 If Samples are to be stored at a location outside the secured area of the Laboratory which first analyzed the Sample, the Laboratory shall secure the A Samples to be shipped either by re-sealing individual bottles with a tamper evident method or by sealing the box in which the Samples are shipped in a manner which ensures Samples integrity and chain of custody. Neither the Athlete nor his or her representative nor an independent witness is required to be present for this procedure.~~

~~5.2.2.12.5 Where Samples are transported to a different facility for long-term storage, the chain of custody reflecting the transfer and receipt at the long term storage facility shall be documented. Transported Samples are not subject to individual inspection by the receiving Laboratory until a Sample has been selected for analysis.~~

~~5.2.2.12.6 During transport and long term storage, Samples shall be maintained at a temperature sufficient to maintain the analytical integrity of the Sample. In any anti doping rule violation case based on the Further Analysis of a stored Sample, the issue of the temperature at which the Sample was transported or stored shall only 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.~~

~~5.1.2.7.15.1.1.1 5.2.2.12.7 The long term storage facility shall maintain security requirements comparable to the security requirements applicable to a Laboratory's short term storage of Samples.~~

~~5.2.2.12.8 Samples held in long-term storage may be selected for Further Analysis at the discretion of the Testing Authority. WADA may also direct the Further Analysis of stored Samples at its own expense. The choice of which Laboratory will perform the Further Analysis will be made by the Testing Authority or WADA. Guidance on which Samples should be subject to Further Analysis is found in the Guidelines for Long-Term Storage.~~

~~5.1.2.7.25.3.4.1.1 5.2.2.12.9 Further Analysis of Samples shall be performed under the ISL and Technical Documents in effect at the time the Further Analysis is performed in a specifically designated area (see ISL Art. 5.2.3.2.4).~~

~~5.2.2.12.10 Further Analysis on long-term stored Samples shall proceed as follows:~~

- ~~• At the discretion of the Testing Authority, the "A" Sample may not be used or it may be used for initial testing (as described in Article 5.2.4.2) only, or for both initial testing and confirmation (as described in Article 5.2.4.3.1). Where confirmation is not completed in the A Sample the Laboratory, at the direction of the Testing Authority shall appoint an independent witness to verify the opening and splitting of the sealed "B" Sample (which shall occur without requirement that the Athlete be notified or present) and then proceed to analysis based on the "B" Sample which has been split into 2 bottles.~~
- ~~• At the opening of the "B" Sample, the Laboratory shall ensure that the Sample is adequately homogenized (e.g. invert bottle several times) before splitting the "B" Sample. The Laboratory shall divide the volume of the "B" Sample into two bottles (using Sample collection equipment compliant to ISTI provision 6.3.4) in the presence of the independent witness. The splitting of the "B" Sample shall be documented in the chain of custody. The independent witness will be invited to seal one of the bottles using a tamper-evident method. If the analysis of the first bottle reveals an Adverse Analytical Finding, the Testing Authority shall use reasonable efforts to notify the Athlete as provided in Article 7.3 of the Code. A confirmation shall be undertaken, using the second sealed bottle, if requested by the Athlete or his/her representative, or if the Testing Authority's reasonable efforts to notify the Athlete have not been successful or at the Testing Authority's election. If the Athlete or his/her representative is not present for the confirmation, then the Laboratory shall appoint an independent witness to observe the opening of the second sealed bottle.~~

~~1.3.2 Sampling and preparation of Aliquots for analysis~~

~~1.3.2.1 The Laboratory shall maintain paper or electronic Laboratory Internal Chain~~

~~of Custody procedures for control of and accountability for all Aliquots and other subsamples and transfers from preparation through to disposal. The procedures shall incorporate the concepts presented in the WADA Technical Document for Laboratory Internal Chain of Custody.~~

~~1.3.2.2 Before the initial opening of a Sample bottle, the device used to ensure the integrity of the Sample (e.g., security tape or a bottle sealing system) shall be inspected and its integrity documented.~~

~~5.1.2.7.35.3.4.1.2 The Aliquot preparation procedure for any Initial Testing Procedure or Confirmation Procedure shall ensure that no minimize the risk of contamination of the Sample or Aliquot exists. The Laboratory shall use new material(s) (e.g. new test tubes) to take Aliquots for Confirmation Procedures.~~

~~1.3.3 Analytical Testing~~

~~1.3.3.1 Urine analysis for adulteration or manipulation~~

~~1.3.3.1.1 The Laboratory shall note any unusual condition of the urine for example: color, odor, turbidity or foam. Only unusual conditions should be recorded and included as part of the report to the Testing Authority.~~

~~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.~~

~~For blood Samples, the Laboratory shall obtain Aliquot(s) from the blood Sample container by using disposable pipettes or pipettes with disposable, non-re-usable tips.~~

~~5.1.2.7.45.3.4.1.3 The Laboratory shall measure the pH and specific gravity-SG 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. (refer to the Technical Document on Endogenous Anabolic Androgenic Steroids Measuring and Reporting, TD EAAS).~~

~~5.3.4.2 Selection of Analytical Testing Procedures~~

~~Standard methods are generally not available for Doping Control analyses. 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.~~

~~5.3.4.3 Measurement Traceability~~

~~5.3.4.3.1 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 Guide 34: 2009* or ISO 17034 should be used.

When a Reference Material is not certified, the Laboratory shall verify its identity and check its purity by comparison with published data and/or by chemical characterization.

5.3.4.3.2 Reference Collections

Urine 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.

5.3.4.4 Validation of Analytical Testing Procedures ^{30, 31}

This Article applies only to the validation of Analytical Testing Procedures, and not to the review of the analytical results for any *Athlete Sample(s)*.

5.3.4.4.1 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 and/or identification and estimation of the concentration of Non-Threshold Substances using Reference Materials. In the absence of suitable Reference Materials, Reference Collections may be used for detection and identification.

5.1.2.7.4.15.3.4.4.1.1 Validation of Initial Testing ProcedureProcedures for Non-Threshold Substances

* until 30 November 2019.

³⁰ Validation results for Analytical Testing Procedures shall be summarized in a Validation Report and supported by the necessary documentation and analytical data. The Validation Report shall indicate whether the Analytical Testing Procedure is Fit-for-Purpose and shall be approved at least by the Laboratory Director and the Laboratory Quality Manager.

³¹ 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).

- The Laboratory shall validate the Selectivity, reproducibility of detection at the MRPL and Limit of Detection (LOD) for the Initial Testing Procedure(s) shall be— from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis. For chromatography-mass spectrometry based 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) (see the Technical Document on Minimum Required Performance Levels, TD MRPL);
- 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.

5.3.4.4.1.2 Validation of Confirmation Procedures for Non-Threshold Substances

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

- Selectivity: The ability of the Confirmation Procedure to detect and identify only the substance 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 Technical Document on Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for *Doping Control* Purposes (TD IDCR) or other applicable Technical Document, Technical Letter or Laboratory Guidelines. The Confirmation Procedure shall be able to discriminate between compounds of closely related structures.
- 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 consistently identified (in compliance with the TD IDCR or other applicable Technical Document, Technical Letter or Laboratory Guidelines). The LOI shall not exceed the applicable MRPL³².

³² The TD MRPL requirement that the LOD, estimated during method validation, shall be equal to or less than 50% of the MRPL, is applicable to the Initial Testing Procedures and not to the Confirmation Procedures. This ensures the detection of the Non-Threshold Substance (or its representative *Metabolite* or characteristic *Marker*, as applicable) at the MRPL at all times, which then triggers the subsequent performance of a Confirmation Procedure. Due to inherent differences between the procedures (e.g. *Sample* preparation) and identification requirements (e.g. number of diagnostic ions or precursor-product ion transitions) applicable to Initial Testing Procedures and

- 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.
- Carryover: The conditions required to eliminate carryover of the substance of interest from *Sample* to *Sample* during processing or instrumental analysis ³³.

5.3.4.4.2 Validation of Analytical Testing Procedures for Threshold Substances

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 using Reference Materials. For Confirmation Procedures, Certified Reference Materials should be used for quantification, if available.

For the application of affinity-binding assays to the analysis of Threshold Substances, the Laboratory shall follow the applicable Technical Document (e.g. Technical Document on human Growth Hormone Isoform Differential Immunoassays for *Doping Control* Analyses, TD GH) or Laboratory Guidelines.

5.3.4.4.2.1 Validation of Initial Testing Procedures for Threshold Substances

- The Laboratory shall validate Initial Testing Procedures that are Fit-for-Purpose, in accordance with relevant WADA Technical Document(s), Technical Letter(s) or Laboratory Guidelines;
- For chromatography-mass spectrometry based Initial Testing Procedures, the Laboratory shall validate the Selectivity, LOD and linear range from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis ³⁴.
- The Laboratory should determine the cut-off levels, based on the estimated concentrations of

Confirmation Procedures, their detection capabilities may differ. Therefore, it may occur that a *Sample* is reported as an *Adverse Analytical Finding* for a Non-Threshold Substance at concentrations lower than the estimated LOD of the Initial Testing Procedure. Furthermore, since LOD values are estimations based on Analytical Method validation with a limited number of representative samples, a Laboratory may be able to effectively confirm the presence of a target Non-Threshold Substance (or its representative *Metabolite* or characteristic *Marker*) in a given *Sample* at levels below the validated LOD (e.g. in a cleaner *Sample* with less matrix interferences).

A Confirmation Procedure for a Non-Threshold Substance shall allow the unequivocal identification of the Non-Threshold Substance (or its representative *Metabolite* or characteristic *Marker*) in compliance with the TD IDCR. If successfully identified, a Non-Threshold Substance can be reported at a concentration below the estimated LOD of the Initial Testing Procedure or the LOI of the Confirmation Procedure.

³³ Elimination of 'injection memory' effect is demonstrated by injecting a negative control sample for the Analyte in question, prepared in the same matrix as the *Sample*, immediately prior to the *Sample* of interest.

³⁴ Unless otherwise specified in a WADA Technical Document, Technical Letter or Laboratory Guidelines.

Threshold Substances, which will require quantitative Confirmation Procedure(s)³⁵. The Laboratory shall validate the reproducibility of determinations at the cut-off level:

- The estimation of Measurement Uncertainty (MU) is not required during the validation of Initial Testing Procedures³⁴.

5.3.4.4.2.2 Validation of Confirmation Procedures for Threshold Substances

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

- Selectivity, LOI, Robustness, Carryover (see ISL Art. 5.3.4.4.1.2).
- 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 Laboratory Guidelines.
- Dynamic/Linear Range: The range of the quantitative Confirmation Procedure shall be documented from at least 50% to 200% of the Threshold value.
- Repeatability (s_r): 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 the Threshold shall be determined.
- Intermediate Precision (s_w): 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 the Threshold shall be determined.
- 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.
- Measurement Uncertainty (MU): The MU associated with the results obtained with the quantitative Confirmation Procedure shall be estimated in accordance with the Technical Document on Decision Limits for the Confirmatory Quantification of Threshold Substances (TD DL) or other applicable Technical Document, Technical Letter or Laboratory Guidelines. At least, MU at levels close to the Threshold shall be determined.

5.3.4.4.2.3 Estimation of Measurement Uncertainty for Quantitative Analyses

³⁵ 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 method's SOP, criteria (e.g. concentration cut-offs), determined during the Initial Testing Procedure method validation, to evaluate initial results as a Presumptive Adverse Analytical Finding and ensure that all potentially positive Samples are subjected to quantitative Confirmation Procedures.

- MU of quantitative results, particularly at or close to the Threshold, shall be addressed during the validation of the quantitative Confirmation Procedure;
- MU is further addressed in the TD DL and other relevant Technical Document(s) (e.g. TD GH) and Laboratory Guidelines;
- 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 or other evidence of method validation in any legal proceeding.

5.3.4.5 Application of Analytical Testing Procedures

5.3.4.5.1 At minimum, all Laboratories are required to implement all mandatory Analytical Testing Procedures³⁶, as determined by WADA in specific Technical Document(s), Technical Letter(s) or Laboratory Guidelines. Laboratories may implement additional methods for the analysis of particular Prohibited Substances or Prohibited Methods.

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 Analytical Method validation documentation or EQAS performance data in support of an Adverse Analytical Finding.

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 ISL 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 Analytical Method validation documentation or EQAS performance data in support of an Adverse Analytical Finding (see ISL Art. 4.4.2.2).

5.3.4.5.2 Laboratories may apply additional Analytical Testing Procedures to analyze Samples for Prohibited Substances or Prohibited Methods not included in the standard Analytical Testing menu or in

³⁶ Mandatory Analytical Testing Procedures are those Analytical Methods for which all Laboratories shall have available analytical capacity, in compliance with relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines, and therefore shall have the Analytical Method included in their Scope of ISO/IEC 17025 Accreditation. However, based on an *In-Competition* or *Out-of-Competition* Analytical Testing menu, a mandatory Analytical Testing Procedure is not necessarily applied to all Samples. For some *Prohibited Substances* or *Prohibited Methods*, Testing Authorities may decide to request Analytical Testing for specific Samples only. These requests shall be detailed in the *Sample* chain of custody. 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. homologous blood transfusion) with a given Analytical Testing Procedure may not be mandatory for all Laboratories. The Laboratory shall report its Analytical Testing menu in ADAMS to inform the *Anti-Doping Organizations* about its available Analytical Testing Procedures.

the Technical Document for Sport Specific Analysis (TD SSA), if the additional work is conducted at the Laboratory's expense and does not significantly affect the possibility to submit the *Sample*, as identified by the Testing Authority or WADA, to Further Analysis. Results from any such analysis shall be reported in ADAMS and have the same validity as any other test result ³⁷.

5.3.4.5.3 Application of Initial Testing Procedures

~~5.1.2.7.4.25.3.4.5.3.1~~ The Initial Testing Procedure(s) applied shall be recorded, as part of the *Sample* (or *Sample* batch) record, each time it is conducted. ~~Laboratories may apply additional accredited test methods to Samples (beyond the client's requested test menu) if the additional work is conducted at the Laboratory's expense and the relevant Samples have not been identified for long term storage.~~

~~1.3.3.1.2 Unless otherwise approved by WADA after consultation with a Testing Authority, the Initial Testing Procedure(s) shall be capable of detecting the Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method for all substances covered by the Prohibited List for which there is a method that is Fit for purpose. WADA may make specific exceptions to this section for specialized techniques that are not required to be within the scope of accreditation of all Laboratories.~~

~~5.3.4.5.3.2~~ The Initial Testing Procedure(s) shall be performed with a Fit for purpose method for the *Prohibited Substance* or *Prohibited Method* being tested, on Aliquot(s) taken from the container identified as the "A-characteristic" *Sample* ³⁸.

~~5.3.4.5.3.3~~ The Initial Testing Procedure(s) shall be Fit-for-Purpose.

~~5.3.4.5.3.4~~ 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*.

³⁷ This does not apply to the analysis of *Prohibited Substances*, which are prohibited *In-Competition* only (as defined in the *Prohibited List*), if the *Sample* has been collected during the *Out-of-Competition* period. For *Out-of-Competition Testing*, Laboratories shall analyze *Samples* only for those *Prohibited Substances* and *Prohibited Methods* that are prohibited at all times (as defined in the *Prohibited List*), as well as for those relevant non-prohibited substances that are included in the WADA Monitoring Program or which are analyzed for result interpretation purposes (e.g. confounding factors of the "steroid profile", non-prohibited substances that share *Metabolite(s)* with *Prohibited Substances*), if applicable.

³⁸ In cases when the "A" *Sample* cannot be used for the Initial Testing Procedure(s), the Initial Testing Procedure may be performed on an Aliquot of the first bottle of the split "B" *Sample*, which is to be used as the "A" *Sample* (see ISL Art. 5.3.1.6).

~~5.1.2.7.4.35.3.4.5.3.5~~ Results from ~~Initial Testing Procedures~~ Procedure(s) can be included as part of longitudinal studies (~~such as e.g.~~ endogenous steroid or haematological profiles), provided that the method is ~~appropriately validated~~ Fit-for-Purpose.

~~5.1.2.7.4.45.3.4.5.3.6~~ All batches undergoing ~~the an~~ Initial Testing Procedure shall include appropriate negative and positive quality controls prepared in the ~~same~~ matrix as the Samples being tested of analysis ³⁹.

~~5.3.4.5.3.7~~ ~~For The Initial Testing Procedures for Non-Threshold Substances-~~ shall include appropriate controls ~~near of representative substance(s) at or below the threshold shall be included in the MRPL.~~

~~5.3.4.5.3.8~~ ~~The Initial Testing Procedures-~~ for Threshold Substances shall include appropriate controls close to the Threshold ³⁹.

~~5.1.2.7.4.55.3.4.5.3.9~~ Results from Initial Testing Procedures are not required to consider the ~~Measurement~~ Uncertainty associated MU ³⁹.

~~5.3.4.5.3.10~~ 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. However, a Presumptive Adverse Analytical Finding from an Initial Testing Procedure is not a necessary condition to perform Confirmation Procedures (e.g. GC/C/IRMS analysis may be performed upon request from the Testing Authority or WADA).

~~5.3.4.5.3.11~~ A Confirmation Procedure for a Non-Threshold Substance with a reporting limit may also be performed if the result estimated from the Initial Testing Procedure is lower than the applicable reporting limit, as determined by the Laboratory in accordance with the Analytical Method's validation results.

~~5.3.4.5.3.12~~ A result obtained in the Initial Testing Procedure for a Threshold Substance higher than the Threshold requires a Confirmation Procedure, even if this result is below the relevant Decision Limit ³⁹. A Confirmation Procedure may also be performed if the result obtained in the Initial Testing Procedure is lower than the Threshold, as determined by the Laboratory in accordance with the method's validation results (see ISL Art. 5.3.4.4.2.1) or as specifically required by the Testing Authority.

~~5.1.2.7.4.65.3.4.5.3.13~~ Performance of a Confirmation Procedure can always be decided by the Laboratory or upon instruction from the Testing Authority. Irregularities in the Initial Testing Procedure(s) shall not in any event invalidate an *Adverse Analytical Finding* when ~~the Confirmation Procedures~~ such is adequately compensates for such irregularities established by a Confirmation Procedure.

³⁹ Unless otherwise specified in a WADA Technical Document, Technical Letter or Laboratory Guidelines.

5.3.4.5.4 ~~Urine~~Application of Confirmation Procedures

1.3.3.2 ~~The Confirmation Procedure~~

5.3.4.5.4.1 ~~Confirmation Procedures(s)~~ shall be ~~documented~~recorded, as part of the Sample (or Sample batch) record~~—, each time it is conducted.~~

5.3.4.5.4.2 The objective of the ~~Confirmation Procedure~~ is to ~~accumulate additional information to obtain a result, which supports or does not~~ support the reporting of an *Adverse Analytical Finding*~~— or Atypical Finding.~~

5.3.4.5.4.3 The Confirmation Procedure(s) shall be Fit-for-Purpose, including the estimation of the MU associated with a quantitative Confirmation Procedure.

~~5.1.2.7.4.75.3.4.5.4.4~~ The ~~Confirmation Procedure~~ shall have equal or greater ~~selectivity than the Initial Testing Procedure~~Selectivity than the Initial Testing Procedure and shall provide accurate quantification results (applicable to Threshold Substances). The Confirmation Procedure should incorporate, when possible and adequate, a different Sample extraction protocol and/or a different analytical methodology⁴⁰.

1.3.3.2.1 ~~“A” Sample~~All batches undergoing a Confirmation

~~5.1.2.7.4.85.3.4.5.4.5~~ A ~~Presumptive Adverse Analytical Finding~~ from an ~~Initial Testing Procedure~~ of a *Prohibited Substance*, *Metabolite(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use of a Prohibited Substance or Prohibited Method* shall be confirmed with an “A” ~~Confirmation Procedure~~ using an additional Aliquot(s) taken from the original “A” ~~Sample~~include appropriate negative and positive quality controls prepared in the matrix of analysis.

For *Prohibited Substances* included in sections S.3 Beta-2 Agonists and S.9 Glucocorticosteroids of the *Prohibited List* only, a Laboratory may contact the ~~Testing Authority~~ regarding a ~~Presumptive Adverse Analytical Finding~~ to enquire whether an approved Therapeutic Use Exemption (TUE) exists for the *Prohibited Substance(s)* detected. Any such contact shall be in writing with a simultaneous copy sent to WADA. The decision by the ~~Testing Authority~~ to proceed with the confirmation, or not proceed with the confirmation based on an approved TUE, shall be communicated by the ~~Testing Authority~~ to the Laboratory in writing. By separate letter, the ~~Testing Authority~~ shall notify WADA of its decision and provide to WADA a copy of the approved TUE.

⁴⁰ Unless otherwise specified in a WADA Technical Document, Technical Letter or Laboratory Guidelines.

5.3.4.5.4.6 Confirmation Procedure Methods

- Mass spectrometry (MS) coupled to ~~either chromatographic separation (e.g. gas (GC) or liquid chromatography (LC))~~ is the analytical technique of choice for confirmation of most Prohibited Substances, Metabolite(s) of a Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method. ~~GC or High Performance Liquid Chromatography (HPLC) coupled with MS or MS-MS. These~~ are acceptable methods for both the Initial Testing Procedures and the Confirmation Procedures if Fit for a specific analyte Purpose.

- Affinity Binding Assays (e.g. Immunoassays), electrophoretic methods and other analytical methods are also routinely used for detection of macromolecules in ~~urine samples.~~ Samples.

- Affinity Binding Assays applied for the Initial Testing Procedures and Confirmation Procedures shall use affinity reagents (e.g. antibodies) recognizing different epitopes of the macromolecule analyzed, unless a purification (e.g. immunopurification) or separation method (e.g. electrophoresis, chromatography) is used prior to the application of the Affinity Binding Assay to eliminate the potential of cross-reactivity. The Laboratory shall document, as part of the method validation, the Fitness-for-purpose of any such purification or separation method.

- In assays which include multiple affinity reagents (such as sandwich immunoassays), only at least one (1) of the affinity reagents (either applied for capture or detection of the target analyte) used in the Affinity Binding Assays applied for the Initial Testing Procedure(s) and Confirmation Procedure(s) must differ for antigenic epitope specificity. The other affinity reagent may be used in both immunoassays.

For analytes that are too small to have two (2) independent antigenic epitopes, two (2) different purification methods or two (2) different analytical methods shall be applied.

- Multiplexed Affinity Binding Assays, protein chips, and similar simultaneous multi-analyte testing approaches may be used.

- Antibodies may also be used for specific labelling of cell components and other cellular characteristics. When the purpose of the test is to identify populations of blood constituents, the detection of multiple Markers on the cells as the criteria for an Adverse Analytical Finding replaces the requirement for two (2) antibodies recognizing different antigenic epitopes.

[Comment: An example is the detection of surface Markers on red blood cells (RBCs) using flow cytometry. The flow cytometer is set up to selectively recognize RBCs. The presence on the RBCs of more than one surface Marker (as determined by antibody labelling) as a criterion for an Adverse Analytical Finding may be used as an alternative to multiple antibodies to the same Marker. The Laboratory shall have a policy to define those circumstances where the]

5.3.4.5.4.7 “A” Sample Confirmation Procedure for an “A” Sample may be repeated (e.g., batch quality control failure) and the first test result shall be nullified. Each repeat confirmation

5.3.4.5.4.7.1 The “A” Confirmation Procedure shall be documented and be performed on using new Aliquot of(s) taken from the container identified as the “A” Sample and new quality control samples⁴¹. At this point, the link between the Sample external code as shown in the Sample container and the Laboratory internal Sample code shall be verified.

5.3.4.5.4.6.25.3.4.5.4.7.2 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 identified/detected by the Initial Testing Procedure(s), the Laboratory shall confirm as many of the Presumptive Adverse Analytical Findings as possible. The decision on the prioritization for the confirmation(s) shall be made to give precedent to the substance(s) with the longest potential period of Ineligibility and the decision should be made in cooperation with the Testing Authority and documented. In addition, no final written Test Report incorporating a Presumptive Adverse Analytical Finding shall be issued unless authorized by the Testing Authority in relation to the existence of an approved Therapeutic Use Exemption (TUE) for the Prohibited Substance as per ISL 5.2.4.3.1.1. reasonably possible (such decision should take into account the volume available in the “B” Sample).

For The confirmation(s) shall prioritize the identification of the Prohibited Substance(s) or Prohibited Method(s) that carry the longest potential period of Ineligibility. The decision should be made in consultation with the Testing Authority and recorded.

5.3.4.5.4.7.3 When there is a Presumptive Adverse Analytical Finding for Amphetamine, Methylphenidate, Beta-2 Agonists, Diuretics, Glucocorticoids or Beta-blockers, or for any other Prohibited Substance or Prohibited Method whose Use has been declared by the Athlete on the DCF, the Laboratory may contact the Testing Authority to enquire whether an approved Therapeutic Use Exemption (TUE) exists for the Prohibited Substance(s) detected^{42,43}. When possible, the Laboratory should provide the concentration

⁴¹ In cases when the “A” Sample cannot be used, the “A” Confirmation Procedure may be performed on an Aliquot of the split “B” Sample (see ISL Art. 5.3.1.6).

⁴² In principle, the enquiry by Laboratories regarding the existence of an approved TUE for a Beta-2 Agonist may be applied not only to those Beta-2 Agonists which are prohibited under any condition, but also to those which are considered Threshold Substances and are permitted by inhalation only up to a maximum dose (e.g. salbutamol, formoterol and salmeterol). In such cases, the Laboratory may enquire about the existence of an approved TUE for the use of a prohibited route of administration or a supra-therapeutic inhalation dose.

⁴³ However, unless there is a prior agreement between the Testing Authority and the Laboratory, contacting the Testing Authority in such cases does not constitute an absolute requirement for the Laboratory. The Laboratory

of the Analyte(s) as estimated during the Initial Testing Procedure. Any such contact with the Testing Authority shall be confirmed in writing (for further guidance, refer to the Laboratory Guidelines on *TUE* enquiries).

The instruction by the Testing Authority on whether the Laboratory shall proceed or not with the confirmation based on an approved *TUE* shall be provided to the Laboratory in writing. If not proceeding with the confirmation, then the Testing Authority shall provide WADA with a copy of the approved *TUE* or the associated *TUE* number if the *TUE* has been submitted into ADAMS.

No final Test Report incorporating a Presumptive Adverse Analytical Finding shall be issued ⁴⁴. In cases when the Testing Authority confirms to the Laboratory the existence of an approved *TUE* for the *Prohibited Substance*, the Laboratory shall report the result as a Negative Finding as instructed by the Testing Authority.

In cases of a resulting *Adverse Analytical Finding* or *Atypical Finding*, the existence or not of an approved *TUE* (or the possibility to obtain a retroactive *TUE*) shall be taken into consideration during the results management process.

5.3.4.5.4.7.4 The Laboratory may repeat the Confirmation Procedure for an “A” *Sample* if appropriate (e.g. quality control failure, chromatographic peak interferences, inconclusive “A” confirmation results). In that case, the previous test result shall be nullified. Each repeat confirmation shall be performed using (a) new Aliquot(s) taken from the “A” *Sample* container and shall be recorded.

5.3.4.5.4.7.5 “A” *Sample* Confirmation Procedure for Non-Threshold Substances

For Non-Threshold Substances without reporting limits, *Adverse Analytical Finding* or *Atypical Finding* decisions for the “A” *Sample* results 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 TD IDCR and/or other relevant Technical Document (e.g. TD MRPL), Technical Letter or Laboratory Guidelines.

For Non-Threshold Substances with reporting limits as specified in the TD MRPL, *Adverse Analytical Finding* decisions for the “A” *Sample* results should be based on the identification of the Non-Threshold Substance or its characteristic *Metabolite(s)* or *Marker(s)*, in compliance with the TD IDCR, at an estimated concentration greater than the reporting limit, unless there is further evidence justifying the reporting of the finding shall be based on the at levels below the reporting limit (e.g. declared use of the *Prohibited Substance* or if the analysis forms part of an ongoing investigation).

may proceed to confirm the Presumptive Adverse Analytical Finding for Amphetamine, Methylphenidate, Beta-2 Agonists, Glucocorticoids, Diuretics, Beta-blockers or a declared *Prohibited Substance* or *Prohibited Method* and report an *Adverse Analytical Finding* in ADAMS according to the confirmation results obtained. In such cases, the existence or absence of an approved *TUE* shall be taken into consideration during the results management process.

⁴⁴ Unless otherwise specified in a WADA Technical Document, Technical Letter or Laboratory Guidelines.

5.3.4.5.4.7.6 "A" Sample Confirmation Procedure for Threshold Substances

For Threshold Substances, *Adverse Analytical Finding* or *Atypical Finding* decisions for the "A" Sample results shall be based on the confirmed identification (in accordance with the TD IDCR, applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance and/or its *Metabolite(s)* or *Marker(s)* and their quantitative determination in the Sample at a level exceeding the value of the relevant Decision Limit, which is specified in the TD DL or other applicable Technical Document(s) (e.g. TD GH) or Laboratory Guidelines. 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).

~~1.3.3.2.1.1—Quantitative Confirmation Procedures for Threshold Substances shall be based on the determination of the mean of the measured analytical values (e.g. concentrations) or ratio calculated from the means of measured analytical values (e.g. concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) "A" Sample Aliquots. That value shall exceed the value of the relevant Decision Limit as specified in the Technical Document on Decision Limits or applicable Guidelines.~~

⁴⁵ If insufficient~~there is not enough~~ Sample volume exists to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed. ~~The reporting of Adverse Analytical~~

~~For endogenous Threshold Substances, Markers of the "steroid profile", or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Finding decisions for the "A" Sample results 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) (e.g. GC/C/IRMS). Atypical Findings for Threshold Substances shall be in compliance with the Technical Document on Decision Limits may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).~~

~~For some exogenous Threshold Substances, which are identified as such in the Prohibited List and the TD DL, Adverse Analytical Finding decisions for the "A" Sample do not require a quantification procedure if detected in the presence of any Prohibited Substance classified under Section S5. "Diuretics and Masking Agents" of the Prohibited List. In such cases, the identification (in accordance to the TD IDCR) of the Threshold Substance and/or its Metabolite(s) in the Sample is sufficient to conclude an Adverse Analytical Finding.~~

5.3.4.5.4.7.5.3.4.5.4.8 "B" Sample Confirmation

~~5.3.4.5.4.7.15.3.4.5.4.8.1 The "B" Sample analysis should occur as soon~~

⁴⁵ Unless otherwise specified in a WADA Technical Document, Technical Letter or Laboratory Guidelines.

~~as possible and should take place no later than seven working days starting the first working day following notification of an "A" Sample Adverse Analytical Finding by the Laboratory, unless the Laboratory is informed that the Athlete has waived his/her right to the "B" confirmation analysis and therefore accepts the findings of the "A" confirmation analysis. A "B" Confirmation Procedure shall be performed using Aliquot(s) taken from the container defined as the "B" Sample.~~⁴⁶

~~5.3.4.5.4.7.25.3.4.5.4.8.2 The "B" Sample confirmation shall be performed in the same Laboratory as the "A" Sample confirmation, unless there are exceptional circumstances, as determined by WADA and with WADA's prior written approval, which prevent the "B" Sample confirmation from being performed in the same Laboratory.~~

~~1.3.3.2.1.2 If the "B" Sample confirmation proves negative, the entire test shall be considered negative.~~

~~1.3.3.2.1.3 For exogenous Threshold Substances, the "B" Sample results shall only confirm the "A" Sample identification for the Adverse Analytical Finding to be valid. No quantification of such Prohibited Substance shall be performed.~~

~~1.3.3.2.1.4 For endogenous Threshold Substances, Adverse Analytical Finding or Atypical Finding decisions for the "B" Sample finding shall be based on the mean of measured analytical values (e.g. concentrations) or ratio calculated from the means of measured analytical values (e.g. concentrations, chromatogram peak heights or areas) of three Aliquots. That mean shall exceed the value of the relevant Threshold as specified in the Technical Document on Decision Limits or applicable Technical Document or Guidelines.~~

~~If insufficient Sample volume exists to analyze three Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.~~

~~5.3.4.5.4.8.3 The Athlete and/or his/her It is the responsibility of the Testing Authority and/or Results Management Authority, as applicable, to inform the Laboratory, in writing, whether the Athlete has waived his/her right to the analysis of the "B" Sample and, therefore, whether or not the "B" Confirmation Procedure will be performed. This information shall be provided within the minimum Sample storage requirements established in ISL Arts. 5.3.2.1 and 5.3.2.2.~~

~~The Testing Authority and/or Results Management Authority, at its discretion, may decide to proceed with~~

⁴⁶ In cases when the "B" Sample cannot be used for Analytical Testing the unopened, sealed "A" Sample may be split (see ISL Article 5.3.1.6) and the "B" Confirmation Procedure(s), if needed, may be performed on an Aliquot taken from the split, resealed "A" Sample fraction designated as the "B" Sample.

the “B” *Sample* analysis, and inform the Laboratory accordingly, even when the *Athlete* waives his/her right to the “B” *Sample* analysis or if the *Athlete* does not respond to requests on his/her decision to perform the “B” *Sample* analysis.

5.3.4.5.4.8.4 The Testing Authority or Results Management Authority should contact the Laboratory to provide information and/or instructions in writing regarding the “B” *Sample* analysis within ten (10) working days following the notification of an “A” *Sample Adverse Analytical Finding* by the Laboratory.

5.3.4.5.4.8.5 The “B” *Sample* confirmation should be performed as soon as possible, and no later than three (3) months, following the reporting of the “A” *Sample Adverse Analytical Finding*.

5.3.4.5.4.8.6 The following non-Laboratory *Persons* shall be authorized to attend the “B” *Sample* Confirmation Procedure:

- ~~The *Athlete* and/or one representative—~~⁴⁷ of the *Athlete* or, in the absence of the *Athlete* and/or representative of the entity responsible for *Sample* collection or results management, a, an Independent Witness ⁴⁸.
- A translator (if applicable);
- A representative of the Testing Authority or the Results Management Authority (if requested by the Testing Authority or the Results Management Authority, respectively);
- A representative of WADA or of WADA’s Independent Observers (IO) Team for Major Events (if requested by WADA or the IO team, respectively);
- ~~A representative of the National Olympic Committee, and/or National Sport Federation, and/or International Federation, and a translator shall be authorized to attend the “B” confirmations as applicable, may also attend the “B” *Sample* opening procedure, upon request and with prior approval by the Laboratory Director.~~

If the *Athlete* declines to be present in person and/or through a representative, or does not indicate whether he or she requests the “B” *Sample* analysis, or if the *Athlete* will not attend (in person or and/or through a representative) once a date and time for the analysis has been proposed or if the *Athlete* or the *Athlete*’s representative does not respond to the invitation or if the *Athlete* or the *Athlete*’s representative continuously claims not to be available on the date or at the time of the opening of the “B” *Sample*, despite reasonable attempts ~~by to find an alternative date and time convenient both to the~~

⁴⁷ The *Athlete* and/or one (1) designated representative, and/or the Independent Witness have the fundamental right to attend the “B” *Sample* opening, aliquoting and resealing procedures. These *Persons* may also have reasonable opportunity to observe other steps of the “B” *Sample* Confirmation Procedure, as long as their presence in the Laboratory does not interfere with the Laboratory’s routine operations or Laboratory safety or security requirements. The *Athlete* may however be represented or assisted by a maximum of two (2) representatives during the initial phase of the “B” *Sample* opening procedure.

⁴⁸ An Independent Witness may also attend even if the *Athlete* is present and/or represented.

~~Athlete and to the Laboratory to accommodate their dates, the Testing Authority or Results Management Authority or WADA, as applicable, shall instruct the Laboratory shall to proceed regardless and appoint an independent witness~~Independent Witness to verify that the "B" Sample container shows no signs of *Tampering* and that the identifying numbers match that on the *Sample* collection documentation. An Independent Witness may be appointed even if the Athlete has indicated that he/she will be present and/or represented.

At a minimum, the Laboratory Director or representative and the *Athlete* or his/her representative and/or the independent witnessIndependent Witness shall sign the Laboratory documentation attesting to the above. A refusal of the Athlete and/or his/her representative, or of the Independent Witness to sign, and the reasons of the refusal, shall be recorded.

5.3.4.5.4.8.7 The timing of the "B" Confirmation Procedure may be strictly fixed in the short term with no postponement possible, when circumstances justify it. This can notably and without limitation be the case in the context of Testing during or immediately before or after Major Events, or when the further postponement of the "B" Sample analysis could significantly increase the risk of Sample degradation.

The Laboratory Director may limit the number of individuals in Controlled Zones of the Laboratory based on safety or security considerations. Persons attending shall not interfere with the "B" Sample opening or the "B" Confirmation Procedure process in any way at any time and shall strictly follow the instructions of the Laboratory. The Laboratory Director may limit the number of individuals in Controlled Zones of the Laboratory based on safety or security considerations.

5.3.4.5.4.7.35.3.4.5.4.8.8 The Laboratory Director may remove, or have any Person removed by proper authority, any, including the Athlete or Athlete's representative(s), if they are not following the instructions, disturbing or interfering with the testing "B" Sample opening or the Analytical Testing process. Any behavior resulting in removal shall be reported to the Testing Authority and may be considered/or Results Management Authority, as applicable. Interference may further be constitutive of an anti-doping rule violation in accordance with Article 2.5 of the Code Art. 2.5, "Tampering, or Attempted Tampering with any part of Doping Control".

1.3.3.2.1.5 Aliquots taken for "B" Confirmation Procedure shall be taken from the original "B" Sample.

The Laboratory shall ensure that the "B" Sample is properly resealed as per provision 5.2.2.12.

5.3.4.5.4.8.9 The Laboratory shall ensure that, after opening and taking Aliquots for the "B" Confirmation Procedure, the "B" Sample is properly resealed in the presence of the Athlete or his/her representative or the Independent Witness, as applicable, who shall all sign the Laboratory documentation attesting to the above. If present, the Athlete or the Athlete's representative shall be offered the opportunity to select the resealing equipment for the "B" Sample container from several

identical/sealed items. A refusal of the Athlete and/or his/her representative, or of the Independent Witness to sign, and the reasons of the refusal, shall be recorded.

5.3.4.5.4.7.45.3.4.5.4.8.10 If more than one (1) Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method has been confirmed in the "A" Confirmation Procedure, the Laboratory shall confirm as many of the Adverse Analytical Findings as possible given the "B" Sample volume available. The decision on the prioritization for the confirmation(s) shall be made to give precedent to prioritize the substance analysis of the Prohibited Substance(s) with or Prohibited Method(s) that carry the longest potential period of Ineligibility and the. The decision should be made in cooperation/consultation with the Testing Authority and documented.

5.3.4.5.4.7.55.3.4.5.4.8.11 The Laboratory shall have a policy to define these circumstances when a may repeat the Confirmation Procedure for thea "B" Sample may be repeated if appropriate (e.g. batch-quality control failure) and the first, chromatographic peak interferences, inconclusive "B" confirmation results). In that case, the previous test result shall be nullified. Each repeat confirmation shall be documented and should be performed on a new using Aliquot of the "B" Sample and new quality control samples(s) different from the one(s) already analyzed. Each Aliquot used shall be recorded.

5.3.4.5.4.8.12 If the final "B" Sample confirmation proves results are negative, the Sample-Analytical Testing result shall be considered negative and a Negative Finding. The Laboratory shall notify the Testing Authority, and WADA and the International Federation notified immediately. The Laboratory shall conduct an internal investigation of the causes of the new discrepancy between the "A" and "B" Sample results and should report its outcomes to the Results Management Authority and WADA within five (5) working days ⁴⁹.

⁴⁹ Target Analytes [e.g. parent compound, Metabolite(s), Marker(s)] used to conclude the presence of a given Prohibited Substance or Use of a Prohibited Method may differ between the Confirmation Procedures of the "A" and the "B" Samples. 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.

5.3.4.5.4.8.13 “B” Sample Confirmation Procedure for Non-Threshold Substances and exogenous Threshold Substances

For Non-Threshold Substances (including those with reporting limits as specified in the TD MRPL) and exogenous Threshold Substances, the “B” Sample results shall only confirm the “A” Sample identification (in compliance with the TD IDCR) for the *Adverse Analytical Finding* to be valid ⁵⁰. No quantification or reported estimation of concentrations of such *Prohibited Substance*, or its *Metabolite(s)* or *Marker(s)* is necessary.

5.3.4.5.4.8.14 “B” Sample Confirmation Procedure for endogenous Threshold Substances

For endogenous Threshold Substances, *Adverse Analytical Finding* or *Atypical Finding* decisions for the “B” Sample results shall be based on the confirmed identification (in accordance with the TD IDCR, applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance or its *Metabolite(s)* or *Marker(s)* and their quantitative determination in the *Sample* at a level exceeding the value of the relevant Threshold as specified in the TD DL or other applicable Technical Document(s) or Laboratory Guidelines. The mean value determined in the “B” Sample does not need to be identical to the mean value determined in the “A” Sample.

“B” Sample quantitative Confirmation Procedures for endogenous Threshold Substances shall be based on the determination of the mean of measured analytical finding-values (e.g. concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) “B” Sample Aliquots ⁵⁰. If there is not enough *Sample* volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

For endogenous Threshold Substances, *Markers* of the “steroid profile”, 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)* (e.g. GC/C/IRMS). *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)*.

5.3.4.5.5 Further Analysis

5.3.4.5.5.1 *Samples* may be selected for Further Analysis at the discretion of the Testing Authority. WADA may also direct the Further Analysis of stored *Samples* at its own expense. In such cases, WADA shall notify the Testing Authority and Results Management Authority, which shall retain ownership of the *Sample(s)* pursuant to ISTI Art. 10.1.

5.3.4.5.5.2 The choice of which Laboratory will conduct the Further Analysis will be made by the Testing Authority or WADA, as applicable.

⁵⁰ Unless otherwise specified in a WADA Technical Document, Technical Letter or Laboratory Guidelines.

5.3.4.5.5.3 Requests to the Laboratory for Further Analysis shall be made in writing and be recorded as part of the Sample's documentation.

5.3.4.5.5.4 Further Analysis of Samples shall be performed under the ISL, Technical Documents, Technical Letters and Laboratory Guidelines in effect at the time the Further Analysis is performed.

5.3.4.5.5.5 Further Analysis 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). However, Further Analysis shall not be aimed at detecting substances or methods, which are no longer prohibited at the time of Further Analysis.

[Further Analysis may not be applied on a Sample, which is the subject of an ongoing Hearing Process, after the responsible Anti-Doping Organization has notified the Athlete that the Sample is a basis for an asserted Code Art. 2.1 anti-doping rule violation, without the consent of the Athlete or approval from the Hearing Body.

When a Sample has been reported as a Negative Finding or Atypical Finding, there is no limitation on the Testing Authority or WADA to conduct Further Analysis on the Sample.

When an Adverse Analytical Finding has been previously reported in relation to a Sample and a Code Art. 2.1 anti-doping rule violation has been asserted against the Athlete (i.e. after results management for a Code Art. 2.1 anti-doping rule violation in relation to the Sample has been completed), Further Analysis should not seek to detect the Prohibited Substance(s) or Prohibited Method(s) that were the basis of the previously asserted anti-doping rule violation. Therefore, the Anti-Doping Organization requesting the Further Analysis should inform the Laboratory of any previous Adverse Analytical Finding reported for the Sample(s) subject to Further Analysis. If previously reported Prohibited Substance(s) or Prohibited Method(s) are detected during the Initial Testing Procedure of Further Analysis, there is no need to conduct the corresponding Confirmation Procedure. However, if the Confirmation Procedure is conducted, and the previously reported Prohibited Substance(s) or Prohibited Method(s) are confirmed, there is no need to report these results again⁵¹. If the results are nevertheless reported, this issue shall be addressed by the Results Management Authority during the results management process].

5.3.4.5.5.6 Further Analysis includes, notably, but without limitation, the application of newly developed or more sensitive Analytical Testing Procedures and/or the analysis of new target Analytes of Prohibited Substance(s) or Prohibited Method(s) [e.g. Metabolite(s) and/or Marker(s)], which were not known or not included in the initial Analytical Testing of the Sample.

Depending on the circumstances, and to ensure an effective and targeted use of the available Sample volume, priorities may be set, and/or the scope of the Further Analysis restricted to specific analyses (in particular, but without limitation, to analyses based on new or improved Analytical Testing Procedures).

5.3.4.5.5.7 Further Analysis shall proceed as follows:

⁵¹ The result should have been already reported in ADAMS and should not be reported again. In the absence of initial instructions, the Laboratory shall seek instructions from the Testing Authority or WADA, as applicable.

- Use of the "A" Sample

The Testing Authority or WADA 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.

- If the Laboratory has been instructed to perform only Initial Testing Procedure(s) on the "A" Sample, any suspicious analytical result obtained from the "A" Sample shall be considered as a Presumptive Adverse Analytical Finding, irrespective of the Analytical Testing Procedure applied, and shall be confirmed using the split "B" Sample (see below).
- When a Confirmation Procedure is performed on the "A" Sample and an Adverse Analytical Finding is reported on this basis, the "B" Sample Confirmation Procedure shall be applicable (as per ISL Art. 5.3.4.5.4.8).

- 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 ISL Art. 5.3.1.6. The Athlete and/or a representative of the Athlete should be invited to witness the splitting procedure. At a minimum, the splitting process shall be conducted in the presence of an appointed Independent Witness.

Even if present during the splitting procedure, the Athlete and/or his/her representative has no right to attend the Analytical Testing Procedures to be performed on the first split fraction of the "B" Sample (unless the Testing Authority requests otherwise)⁵². In the event an Adverse Analytical Finding is notified based on the results of a Confirmation Procedure of the first fraction of the "B" Sample, the second split fraction of the "B" Sample shall be deemed as the "B" Sample. If applicable, a "B" confirmation shall be decided and performed in accordance with ISL Art. 5.3.4.5.4.8.

5.3.4.5.5.8 Further Analysis may be performed on stored Samples that were previously reported as having Adverse Analytical Findings or Atypical Findings. Any new Prohibited Substance or Prohibited Method detected shall be reported even if the Athlete was already sanctioned for a different Adverse Analytical Finding⁵³.

5.3.4.5.5.9 Previously acquired Initial Testing Procedure data may also be re-evaluated for the presence of Prohibited Substances or their Metabolites(s) or Markers(s) of Prohibited Substances or Prohibited Methods, at the initiative of the Testing Authority, the Results Management Authority, WADA

⁵² 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).

⁵³ See ISL Article 5.3.4.5.5.5 with respect to the reporting of Prohibited Substance(s) or Prohibited Method(s) previously reported as an Adverse Analytical Finding.

or the Laboratory itself. The results of such re-evaluation, if suspicious, shall be communicated to the Testing Authority, the Results Management Authority or WADA, as applicable, and may lead to Further Analysis.

~~5.1.2.7.55.3.4.5.6~~ Alternative ~~biological matrices~~ Biological Matrices

Any ~~testing/negative~~ Analytical Testing results obtained from hair, nails, oral fluid or other biological material shall not be used to counter *Adverse Analytical Findings* or *Atypical Findings* from urine- ~~or blood (including whole blood, plasma or serum).~~

~~5.1.35.3.5~~ Results ~~management~~ Management

~~5.3.5.1~~ Review of Results

~~1.3.3.3~~ The Laboratory shall conduct a minimum of two (2) independent reviews of all Initial Testing Procedure raw data and results

~~5.3.5.1.1~~ . The review process shall be recorded.

~~5.1.3.1.15.3.5.1.2~~ A minimum of two ~~certifying scientists~~ (2) Certifying Scientists shall conduct ~~a separate and impartial~~ an independent review of all *Adverse Analytical Findings* and *Atypical Findings* before a ~~report/test result~~ is issued. ~~The review process~~ reported. Evidence of the review and approval of the analytical run/batch shall be recorded.

~~5.1.3.1.25.3.5.1.3~~ At a minimum, the review of *Adverse Analytical Findings* and *Atypical Findings* shall include:

- Documentation linking the *Sample* external code (as specified in the DCF) to the Laboratory internal *Sample* code;
- Laboratory Internal Chain of Custody documentation;
 - ~~Laboratory Internal Chain of Custody documentation;~~
- Validity of the *Initial Testing Procedure(s)* and *Confirmation Procedure(s)* analytical ~~initial and confirmatory~~ data and calculations;
- Quality control data;
- Completeness of technical and analytical documentation supporting the reported ~~analytical~~ findings;
- Compliance of test data with the Analytical Testing Procedure's validation results (e.g. MU);
- Assessment of the existence of significant data or information that would cast doubt on or refute

the Laboratory findings ⁵⁴.

- When ~~an~~ the Confirmation Procedure result(s) are rejected as *Adverse Analytical Finding(s)* or *Atypical Finding* ~~is rejected(s) based on the results review~~, the reason(s) for the rejection shall be recorded.

5.1.3.2.5.3.5.2 Documentation and ~~reporting~~ Reporting

5.1.3.2.15.3.5.2.1 The Laboratory shall have documented procedures to ensure that it maintains a ~~coordinated~~ 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 Technical Document on Laboratory Documentation Packages (TD LDOC).

5.1.3.2.25.3.5.2.2 Each step of Analytical Testing shall be traceable to the staff member who performed that step.

5.1.3.2.35.3.5.2.3 Significant ~~variance~~ deviation from ~~the~~ a written ~~procedure~~ SOP shall be documented as part of the record (e.g., ~~memorandum for the record~~) recorded.

5.1.3.2.45.3.5.2.4 Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record.

5.3.5.2.5 Reporting of "A" *Sample* results should occur in ADAMS within ~~ten~~ fifteen (15) working days of receipt of the *Sample*.

The reporting time required for specific ~~Competitions~~ occasions (e.g. Major Events) may be substantially less than ~~ten~~ fifteen (15) working days.

~~1.3.3.4~~ The reporting time may be altered by agreement between the Laboratory and the Testing Authority.

The Testing Authority should be informed of any delay in the reporting of "A-single, distinct-" Sample results.

5.3.5.2.6 Test Report ~~and/or ADAMS~~

5.1.3.2.415.3.5.2.6.1 The Laboratory shall ~~record~~ shall be generated to document the ~~Adverse Analytical Finding(s) or Atypical Finding(s) of an~~ the test result for each individual *Sample*. ~~The Laboratory Test Report shall include, in addition to the~~ in ADAMS with the mandatory information

⁵⁴ 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.

stipulated, in compliance with the relevant Technical Document, Technical Letter or Laboratory Guidelines, the items stipulated in ISO/IEC 17025, and the following:

- ~~Sample code;~~
- ~~Laboratory identification code;~~
- ~~Type of test (Out of Competition/In Competition);~~
- ~~Sport and/or discipline;~~
- ~~Name of Competition and/or Customer reference code (for example: ADAMS test mission code), if provided by the Testing Authority;~~
- ~~Date of Collection;~~
- ~~Date of receipt of Sample;~~
- ~~Date of report;~~
- ~~Sex of the Athlete;~~
- ~~Type of Sample (urine, blood, etc.);~~
- ~~Test results (for Threshold Substances in compliance with the Technical Document on Decision Limits);~~
- ~~The name of the Sample Collection Authority;~~
- ~~The name of the Testing Authority;~~
- The name of the Results Management Authority, if provided;
 - ~~Signature of authorized individual;~~
 - ~~Other information as specified by the Testing Authority and/or WADA.~~

At a minimum, ~~labelling and information provided by the Laboratory related to the type of test, sport/discipline, test results (including comments/opinions) and client to whom the report is addressed shall also be provided in English on the test report.~~

~~[Comment: A complete analytical test report generated from ADAMS should be considered to have fulfilled the above requirements and therefore should be regarded as an official test report.]~~

 - Relevant comments if necessary for proper interpretation of the test result or recommendations to the Testing Authority (for example, for Target Testing of the Athlete) – see ISL Art. 5.3.5.2.6.6;
 - Specific tests performed, in addition to the Laboratory routine test menu (e.g. ESA, GC/C/IRMS, hGH, blood transfusions, DNA, genomic profiling, etc.);
 - Any irregularities noted on Samples.

5.3.5.2.6.2 The Laboratory is not required to provide any additional Test Report, either in hard copy or digital format, other than the submission in ADAMS (except as described in ISL Arts. 5.3.5.2.6.8 and 5.3.5.2.6.12). All Code-compliant Testing Authorities shall be able to access the Test Reports of their Samples in ADAMS. The Laboratory should record the ADAMS Test Report as part of the Sample's documentation.

5.3.5.2.6.3 Test Report for Non-Threshold Substances

- "A" Sample Test Report

The Laboratory is not required to ~~quantify or report a concentration~~ concentrations for an analyte of ~~non-threshold Prohibited~~ Non-Threshold Substances in urine Samples. 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), or Marker(s) detected* present (i.e. identified, as per the TD IDCR) in the ~~urine Sample. Upon~~ and in accordance with the reporting requirements established in the TD MRPL ⁵⁵.

However, the Laboratory should provide estimated concentrations when possible and for information purposes only, upon request ~~of by~~ the Testing Authority, Results Management Authority or WADA, if the detected level of the Non-Threshold Substance(s), its *Metabolite(s)*, or *Marker(s)* may be relevant to the results management of an anti-doping case. In such instances, the Laboratory should indicate the estimated concentration while making it clear to the Testing Authority, Results Management Authority or WADA ~~and where~~ that the concentration was obtained by an Analytical Testing Procedure, which has not been validated for quantitative purposes.

- "B" Sample Test Report

For Non-Threshold Substances, the Laboratory report 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 TD IDCR or other applicable Technical Document(s) ⁵⁵.

However, the Laboratory should provide estimated concentrations, when possible and for information purposes only, if requested by the Testing Authority, Results Management Authority or WADA, if the detected level of ~~a Prohibited~~ the Non-Threshold Substance ~~is~~(s), its *Metabolite(s)*, or *Marker(s)* may be relevant to ~~the result~~ results management of an anti-doping case. In such instances, the Laboratory should ~~provide an approximate~~ indicate the estimated concentration while making it clear to the Testing Authority, Results Management Authority or WADA that the concentration was obtained by an Analytical Testing Procedure, which has not been validated for quantitative purposes. Differences in the estimation of the detected levels of Non-Threshold Substance(s), its *Metabolite(s)*, or *Marker(s)* between the "A" and "B" Confirmation Procedures do not affect the validity of the reported results.

5.3.5.2.6.4 Test Report for Threshold Substances

- "A" Sample Test Report

⁵⁵ When applicable, the Laboratory shall record in the ADAMS Test Report the specific *Metabolite(s)* or *Marker(s)* of the Non-Threshold Substance that were identified in the Sample.

For ~~Threshold Substances in urine Samples~~, the ~~Laboratory report~~ Test Report for the "A" Sample shall establish that the identified Prohibited Substance(s) or its Metabolite(s) or Marker(s) is present at a concentration and/or ratio and/or score of measured analytical values greater than the DL, and/or that the Prohibited Substance(s) or its Metabolite(s) or Marker(s) is of exogenous origin.

In the event that the Threshold Substance(s), which are identified as such in the Prohibited Method List and the TD DL, is (are) detected in the presence of (a) diuretic(s) or masking agent(s), the Laboratory shall establish the presence (i.e. the identity) of the Prohibited Substance(s) and/or its Metabolite(s) in accordance with the TD IDCR and the TD DL and report it as an Adverse Analytical Finding, in addition to the reporting of the diuretic(s) or masking agent(s). In such cases, the Laboratory should report the estimated concentration of the Threshold Substance(s), indicating that the levels detected may have been impacted by the presence of the diuretic(s) or masking agent(s).

- "B" Sample Test Report

For exogenous Threshold Substances, the Laboratory Test Report 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 TD IDCR.

For endogenous Threshold Substances, the Laboratory Test Report for the "B" Sample shall establish that the identified Prohibited Substance(s) or its Metabolite(s) or Marker(s) is present at a concentration and/or ratio and/or score of measured analytical values greater than the Decision Limit in accordance with the reporting requirements as described in the relevant Technical Document Threshold, and/or that the Prohibited Substance(s) or its Metabolite(s) or Marker(s) is of exogenous origin.

In the event that the Threshold Substance(s), which are identified as such in the Prohibited List and the TD DL, is (are) detected in the presence of (a) diuretic(s) or masking agent(s), the Laboratory shall establish the presence (i.e. the identity) of the Prohibited Substance(s) and/or its Metabolite(s) in accordance with the TD IDCR and the TD DL and report it as an Adverse Analytical Finding, in addition to the reporting of the masking agent(s). In such cases, the Laboratory shall report the estimated concentration of the Threshold Substance(s), indicating that the levels detected may have been impacted by the presence of the diuretic(s) or masking agent(s).

5.1.3.2.4.25.3.5.2.6.5 The Laboratory shall qualify the result(s) of the analysis in the ADAMS Test Report as:

- Adverse Analytical Finding; or
- Atypical Finding; or
 - In the absence of the above results, a qualification indicating that no Prohibited Substance(s) or Prohibited Method(s) or their Metabolite(s) or Marker(s) were detected on the test menu.
- Negative Finding; or

- Not-Analyzed: any *Sample* received at the Laboratory and not subject to Analytical Testing for a valid, documented reason such as *Sample irregularities, intermediate Samples, etc.* (see ISL Arts. 5.3.1.5.2 and 5.3.1.5.3).

5.1.3.2.4.35.3.5.2.6.6 The Laboratory shall have a policy regarding the provision of opinions and interpretation of data. An opinion or interpretation may be included in the ADAMS 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.

[Comment: 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 Testing investigations regarding potential environmental contamination causes and/or Further Analysis and whether an observed result is consistent with a set of reported conditions.]

~~1.3.3.5—The Laboratory shall report all test results as defined in ISL provision 5.2.6.8 via ADAMS and simultaneously only to the relevant Testing Authority and/or the responsible International Federation and/or to the Major Event Organizations (in the case of Major International Events) not using ADAMS. The information provided in ADAMS shall be in compliance to ISL provision 5.2.6.6. In the case where the sport or Event is not associated with an International Federation (e.g., Professional Leagues, University and College sports) the Laboratory should report Adverse Analytical Findings to the Testing Authority and to WADA. All reporting shall be in accord with the confidentiality requirements of the Code.~~

~~1.3.3.6—The Laboratory, upon request by the Testing Authority, Results Management Authority, or WADA may be asked to review data from longitudinal studies. Following review of the applicable data, a report and recommendation shall be made by the Laboratory to the Testing Authority, Results Management Authority or WADA as to whether the data supports an Adverse Analytical Finding or not. If the Testing Authority, Results Management Authority or WADA has concluded an Adverse Analytical Finding, the Laboratory will be informed and shall conduct the “B” confirmation analysis according to section 5.2.4.3.2.~~

~~1.3.3.7—Upon request, the Laboratory shall report in a format specified by WADA, a summary of the results of analyses performed. No information that could link an Athlete’s identify with an individual result will be included. The report will include a summary of any Samples rejected for Analytical Testing and the reason for the rejection.~~

~~1.3.3.8—The documentation package should be provided by the Laboratory only to the relevant Results Management Authority upon request and should be provided within ten working days of the request. Laboratory Documentation Packages shall be in compliance with the WADA Technical Document on Laboratory Documentation Packages.~~

~~1.3.3.9—Athlete confidentiality shall be respected by all Laboratories engaged in~~

~~Doping Control cases:~~

~~1.3.3.9.1 Testing Authority, Results Management Authority or WADA requests for information shall be made in writing to the Laboratories.~~

5.3.5.2.6.7 The Laboratory may request a second opinion from other Laboratory(-ies) before reporting an Adverse Analytical Finding or Atypical Finding. Such requests for second opinions may be required by specific WADA Technical Document(s), Technical Letters or Laboratory Guidelines, required by WADA from certain Laboratory(-ies) for all or for specific Analytical Testing Procedures under certain conditions (e.g. following 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 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 responsibility for the result shall be of the Laboratory that performed the analysis and issued the final Test Report.

5.3.5.2.6.8 Upon request by WADA, the Laboratory shall report a summary of the results of analyses performed in a format specified by WADA.

5.3.5.2.6.9 Confidentiality of the analytical data and Athlete's identity shall be observed by all parties (e.g. Laboratory, Testing Authority, Results Management Authority, WADA, other parties informed including, where different, International Federations, National Olympic Committees, National Federations).

5.3.5.2.6.10 Requests for information by the Testing Authority, Results Management Authority or WADA to a Laboratory shall be recorded in writing.

~~5.1.3.2.4.45.3.5.2.6.11 Presumptive Adverse Analytical Findings- (when applicable – see ISL Art. 5.3.4.5.4.7.3). Adverse Analytical Findings and Atypical Findings and Atypical Findings shall not be provided by telephone reported in writing.~~

~~Information sent by a facsimile is acceptable if the security of the receiving facsimile machine has been verified and procedures are in place to ensure provided that the correct facsimile number is verified prior to transmission and the receipt is verified after the facsimile has been transmitted to the correct facsimile number.~~

~~Unencrypted email is not authorized for any~~ Encrypted emails or documents shall be used for reporting or discussion of Adverse Analytical Findings or Atypical Findings if the Athlete can be identified or if any information regarding the identity of the Athlete is included.

5.3.5.2.6.12 The Laboratory shall also provide any information requested by WADA in relation to the Monitoring Program (Article Code Art. 4.5).

5.3.5.2.7 Laboratory Documentation Package and Certificate of Analysis

~~5.1.3.2.4~~ ~~5.3.5.2.7.1~~ Laboratory Documentation Packages and Certificates of Analysis shall be in compliance with the ~~Code~~ TD LDOC.

~~1.4~~ — Quality Management Processes

~~5.3.5.2.7.2~~ 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.

~~5.3.5.2.7.3~~ The Laboratory Documentation Package and/or Certificate of Analysis should be provided by the Laboratory only to the relevant Results Management Authority or WADA upon request and should be provided within fifteen (15) working days of the request, unless a different deadline is agreed with the Results Management Authority or WADA, respectively.

5.4 Management Requirements

~~5.1.4~~ 5.4.1 Organization

~~5.1.4.1~~ 5.4.1.1 Within the framework of ISO/IEC 17025, the Laboratory shall be considered as a testing laboratory.

~~5.1.4.2~~ 5.4.1.2 The Laboratory Director shall have the responsibilities of the Chief Executive of the Laboratory, unless otherwise noted.

5.4.2 Assuring the Quality ~~policy~~ of Analytical Results

5.4.2.1 The Laboratory shall participate in the WADA EQAS.

~~5.1.4.3~~ 5.4.2.2 Analytical performance shall be monitored by operating quality control schemes appropriate to the type and objectives frequency of Analytical Testing performed by the Laboratory. The range of quality control activities include, but are not limited to:

- ~~The~~ Appropriate positive and negative quality control samples (QCs) shall be included in every analytical run both for the Initial Testing Procedure(s) and Confirmation Procedure(s) ⁵⁶.
- Appropriate internal standard(s) shall be used for chromatography methods;
- For Threshold Substances, quality control charts (QC-charts) referring to appropriate control limits depending on the Analytical Testing Procedure employed (e.g. +/- 2SD; +/- 3SD; +/- $U_{95\%}$), shall be regularly used to monitor method performance and inter-batch variability (when applicable).

5.4.2.3 Internal Quality Policy and implementation shall Assurance Scheme (iQAS)

5.4.2.3.1 The Laboratory shall establish a functional and robust iQAS program, in accordance with the

⁵⁶ Unless otherwise specified in a WADA Technical Document, Technical Letter or Laboratory Guidelines.

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 into ADAMS.

5.4.2.3.2 The iQAS plan shall include the proficiency testing of 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.

5.4.2.3.3 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).

5.4.2.4 Internal Audits

Internal audits shall be completed 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).

Internal audit responsibilities may be shared amongst personnel provided that any Person does not audit his/her own area.

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.

5.4.2.5 External Audits

Laboratories may also consider having their procedures and systems audited by other Laboratory Directors or external auditing experts. However, this shall not replace the performance of internal audits by the Laboratory.

5.4.2.6 All quality control procedures shall be documented by the Laboratory.

5.4.3 Management Reviews

Management reviews will be conducted to meet the requirements of ISO/IEC 17025 Section 4.2 Management System and shall include a quality manual that describes the quality system.

1.4.1.1 A single staff member should be appointed as the Quality Manager and shall have responsibility and authority to implement and ensure compliance with the quality system.

5.1.5.4.4 Document ~~control~~Control

The control of documents that make up the Management System shall meet the requirements of ISO/IEC 17025 Section 4.3 Document Control.

~~5.1.5.15.4.4.1~~ The Laboratory Director (or designee) shall approve the Quality Manual-Management System documentation and all other documents used by staff members involved in completing Analytical Testing.

~~5.1.5.25.4.4.2~~ ~~The~~ The Laboratory shall implement a procedure in its Management System ~~shall to~~ ensure that the contents of ISL, WADA Technical Documents, Technical Letters and Laboratory Guidelines are incorporated into the ~~appropriate manuals~~ Laboratory's SOPs by the applicable effective date and that ~~training implementation is provided completed, assessed, audited and recorded~~. If this is not possible, ~~WADA~~ the Laboratory shall ~~be contacted with~~ send a written request for an extension beyond the applicable effective date for consideration by WADA. Any failure by the Laboratory to implement mandatory requirements by the established effective date, without a prior approval by WADA, shall be considered a noncompliance and may affect the Laboratory accreditation status.

5.4.5 Control and Storage of Technical Records

5.4.5.1 A copy of all Samples' records, including Sample and Aliquot chain of custody, instrument records, calculations, etc., shall be kept in a secure storage for a minimum of two (2) years. After two (2) years, and up to ten (10) years, the relevant records shall be kept in secure storage until Sample disposal.

5.4.5.2 An electronic copy of the analytical raw data and any data analysis review files shall be stored for ten (10) years for all Samples.

5.4.6 Control of Nonconformities in Analytical Testing

5.4.6.1 The Laboratory shall have policies and procedures that shall be implemented when any aspect of its Analytical Testing does not comply with set requirements.

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

5.4.6.3 Risk Minimization

Laboratories shall take corrective actions in accordance with ISO/IEC 17025 and WADA Laboratory Guidelines for Corrective Action Investigation and Reporting.

When conducting a corrective action investigation, the Laboratory shall perform a thorough Root Cause Analysis of the nonconformity.

5.4.6.4 Improvement

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

~~5.4.6~~5.4.7 Reviewing of ~~requests, tenders,~~Requests, Tenders and ~~contracts~~Contracts

Review of legal documents or agreements related to ~~testing~~Analytical Testing shall meet the requirements of ISO/IEC 17025 ~~Section 4.4.~~

~~The Laboratory shall ensure that the Testing Authority is informed concerning the Prohibited Substances that can be detected under the scope of accreditation in Samples submitted for analysis.~~

~~5.4.7~~5.4.8 Subcontracting of ~~tests~~Analysis

~~5.4.7.15~~5.4.8.1 A ~~WADA-accredited laboratory~~Laboratory or WADA-Approved Laboratory for the ABP shall perform all work with qualified personnel and equipment within its accredited ~~or approved~~ facility, respectively.

~~5.4.7.25~~5.4.8.2 ~~A Laboratory may subcontract an analysis to another Laboratory, in consultation with the Testing Authority (for example, in the case of a specific technology or Analytes that are not within the scope of accreditation of the Laboratory, a Sample may be transferred to another Laboratory where the Laboratory's Scope of ISO/IEC 17025 Accreditation, an Analytical Testing Restriction decision, or as a result of other justifications such as a need for higher sensitivity or specific technology is within the scope of its accreditation equipment or expertise, workload or temporary technical incapacity).~~ In exceptional circumstances, WADA may elect to grant specific authorization to subcontract ~~the analysis of a Sample~~analyses using a ~~special technique not required in Laboratory-specific methods,~~ to an ISO/IEC 17025-accredited laboratory, approved by WADA, ~~that which~~ has this technique within its ~~scope of accreditation~~Scope of ISO/IEC 17025 Accreditation (for example, DNA analysis or genomic profiling). 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 Laboratory⁵⁷. In all such cases, ~~assurance of the the Laboratory subcontracting the analysis is only responsible for the maintenance of the level of quality and the appropriate chain of custody throughout the entire process is the responsibility of the up to Sample reception by the subcontracted Laboratory~~Director. Such arrangements shall be clearly ~~documented~~recorded as part of the ~~Sample record~~Sample's documentation and included in the Laboratory Documentation Package, if applicable.

5.4.8.3 When subcontracting an analysis, Laboratories should follow the WADA Laboratory Guidelines on "Conducting and Reporting Subcontracted Analysis and Further Analysis for Doping Control".

⁵⁷ Or directly contracted by the Testing Authority. In this case, the Laboratory shall nevertheless be in charge of ensuring the Sample chain of custody in connection with the transfer of the Sample to the other Laboratory or expert as the case may be.

~~5.1.8.15.4.9~~ Purchasing of ~~services~~Services and ~~supplies~~Supplies

~~5.1.8.15.4.9.1~~ Chemicals and ~~reagents~~Reagents

~~5.1.8.15.4.9.1.1~~ Chemicals and reagents shall be ~~suitable~~Fit for the purpose of the analysis Purpose and be of ~~established~~appropriate purity. ~~Reference~~Documentation indicating the purity ~~documentation of Reference Materials/Standards~~ shall be obtained when available and retained in the ~~quality system~~Management System documents. 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~~Purpose by the ~~Laboratory~~ and/or WADA.

~~5.1.8.15.4.9.1.2~~ In the case of rare or difficult to obtain ~~Reference Materials~~, or ~~Reference Collections~~, particularly for use in qualitative ~~methods~~Analytical Testing Procedures, the expiration date of the solution can be extended if adequate documentation exists confirming that no significant deterioration ~~that would preclude obtaining an acceptable mass spectrum~~ has occurred. ~~In the case of rare or difficult to obtain reagents the expiration date can be extended if 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.~~

~~5.4.9.1.3~~ The Laboratory shall maintain control and proper records of use of controlled chemicals and reagents in accordance with national laws and other relevant regulations.

~~5.1.8.15.4.9.1.4~~ Waste disposal shall be in ~~accord~~accordance with national laws and other relevant regulations. This includes biohazard materials, chemicals, controlled substances, and radioisotopes, if used.

~~5.1.8.15.4.9.1.5~~ Environmental health and safety policies shall be in place to protect the staff, the public, and the environment.

~~1.4.2~~ Service to the customer

~~5.4.10~~ Service to ~~Cooperation with Customers and with WADA~~

~~5.1.8.25.4.10.1~~ Cooperation with customers shall be handled in ~~accord~~accordance with ISO/IEC 17025 ~~Section 4.7~~.

~~5.1.8.35.4.10.2~~ Ensuring ~~responsiveness~~Responsiveness to WADA

The ~~Laboratory~~ Director or his/her designee shall:

- Ensure adequate communication ~~with WADA~~ in a timely manner;
- ~~Provide complete, appropriate and timely explanatory information as requested by WADA;~~
- Report to WADA any unusual circumstances or information with regard to ~~Analytical Testing~~, patterns of irregularities in ~~Samples~~, or potential ~~use~~Use of new substances;

~~• Provide complete and timely explanatory information to WADA as appropriate and as requested;~~

- Provide documentation to WADA (e.g. ~~quality manual~~ Management System documentation, SOPs, contracts ~~with Code-signatory clients or Testing Authorities~~ (not including commercial or financial information)) with Testing Authorities, which are Code-compliant Anti-Doping Organizations, as determined by WADA, or Sample Collection Authorities working on behalf of Code-compliant Anti-Doping Organizations upon request to ensure conformity with the rules established under the Code as part of the maintenance of WADA accreditation. This information ~~will~~ shall be treated in a confidential manner.

5.1.8.4.10.3 Ensuring ~~responsiveness~~ Responsiveness to Testing Authority and/or Results Management Authority

The Laboratory Director shall be familiar with the Testing Authority rules and the *Prohibited List*.

The Laboratory Director shall interact with the Testing Authority ~~with respect~~ and/or Results Management Authority in regard to specific timing, report information, or other support needs. These interactions should occur in a timely manner and should include, but are not limited to, the following:

- Communicating with the Testing Authority and/or Result Management Authority concerning any significant question of Analytical Testing needs or any unusual circumstance in the Analytical Testing process (including delays in reporting);
 - ~~• Acting without bias regarding the national affiliation of the Testing Authority and/or Result Management Authority;~~
- Providing complete ~~and~~ timely and unbiased explanations to the Testing Authority and/or Result Management Authority 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;
 - If requested by the Testing Authority, the Laboratory shall provide advice and/or opinion to the Testing Authority regarding the Prohibited Substances and Prohibited Methods included in the Analytical Testing Procedures;
- Providing evidence and/or expert testimony on any test result or report produced by the Laboratory as required in administrative, arbitration, or legal proceedings;
- Responding to any complaint submitted by a Testing Authority or Anti-Doping Organization Results Management Authority concerning the Laboratory and its operation.

5.1.8.4.15.4.10.3.1 ~~The~~ As required by ISO/IEC 17025, the Laboratory shall actively monitor the quality of the services provided to the relevant ~~anti-doping authorities~~ Organizations, including the introduction of an annual questionnaire to clients to assess their satisfaction (or otherwise) with the performance of the Laboratory. There should be documentation that the Testing Authority or Results Management Authority concerns have been incorporated into the Laboratory Laboratory's Management

System where appropriate.

~~1.4.2.1.1 The Laboratory shall develop a system, as required by ISO/IEC 17025 for monitoring Laboratory service.~~

~~5.4.95.4.11~~ Complaints

Complaints shall be handled in accordance with ISO/IEC 17025 ~~Section 4.8~~.

~~1.4.3~~ Control of nonconformities in Analytical Testing

~~1.4.3.1 The Laboratory shall have policies and procedures that shall be implemented when any aspect of its Analytical Testing or a result from its analyses does not comply to set procedures.~~

~~1.4.3.2 Documentation of any non-compliance or departure from procedure or protocol involving analysis of a Sample shall be kept as part of the Sample record.~~

~~1.4.4~~ Improvement

~~The Laboratory shall continually improve the effectiveness of its management system in accordance with ISO/IEC 17025 Section 4.10.~~

~~1.4.5~~ Corrective action

~~Corrective action shall be taken in accordance with ISO/IEC 17025 Section 4.11.~~

~~1.4.6~~ Preventive action

~~Preventive action shall be taken in accordance with ISO/IEC 17025 Section 4.12.~~

~~1.4.7~~ Control and storage of technical records

~~A copy of all records (chain of custody, instrument records, electronic analytical data, steroid profile, calculations, etc.) supporting the analyses shall be kept in a secure storage for a minimum of two years. After two years, these records shall be kept in secure storage for as long as the relevant Samples are stored at the Laboratory or in long-term storage (until disposal).~~

~~An electronic copy of the analytical data for all Samples shall be stored for ten years for all Samples.~~

~~1.4.8~~ Internal audits

~~1.4.8.1 Internal audits shall be completed in accordance with the requirements of ISO/IEC 17025 Section 4.14.~~

~~1.4.8.2—Internal Audit responsibilities may be shared amongst personnel provided that any person does not audit his/her own area.~~

~~1.4.9—Management reviews~~

~~Management reviews will be conducted to meet the requirements of ISO/IEC 17025 Section 4.15.~~

~~1.5—Support Processes~~

~~1.5.1—General~~

~~General support shall be provided in accordance with the requirements of ISO/IEC 17025 (Section 5.0).~~

~~1.5.2—Personnel~~

~~1.5.2.1—Every person employed by, or under contract to, the Laboratory shall have an accessible personnel file which shall contain copies of the curriculum vitae or qualification form, a job description, and records of initial and ongoing training. The Laboratory shall maintain appropriate confidentiality of personal information.~~

~~1.5.2.2—All personnel shall have a thorough knowledge of their responsibilities including the security of the Laboratory, confidentiality of results, Laboratory Internal Chain of Custody protocols, and the standard operating procedures (SOPs) for any method that they perform.~~

~~1.5.2.3—The Laboratory Director is responsible for ensuring that Laboratory personnel are adequately trained and have experience necessary to perform their duties. The approval, as well as supporting training records, shall be retained in the individual's personnel file.~~

~~1.5.2.4—The Laboratory shall have a qualified person as the Laboratory Director to assume professional, organizational, educational, and administrative responsibility. The Laboratory Director qualifications are:~~

- ~~• Ph.D. (or equivalent) in one of the natural sciences or M.D. (or equivalent) with appropriate and comparable experience and/or training in bioanalysis, preferably in the anti-doping area. In the absence of a PhD, extensive and appropriate anti-doping science experience and training (e.g. a senior Laboratory position for a minimum of ten years), including the documented ability to develop and conduct research projects;~~
- ~~• Experience and competence in the analysis of biological material for substances used in doping;~~

- ~~Appropriate training or experience in forensic applications of *Doping Control*. It is acknowledged that the Laboratory Director plays an essential role in the anti-doping Laboratory operations and that the WADA accreditation is delivered based upon such qualification as well as the Laboratory operational performance. WADA shall be immediately informed of the appointment of a new Laboratory Director. WADA reserves the right to review the credentials of such appointment in accordance with the above qualifications;~~
- ~~Any personnel changes to this position shall be communicated to WADA no later than one (1) month prior to the scheduled date the Laboratory Director vacates his/her position. A succession plan shall be forwarded to WADA.~~

1.5.2.5 ~~The Laboratory shall have qualified personnel to serve as Certifying Scientist(s) to review all pertinent data, quality control results, and to attest to the validity of the Laboratory's test reports. The qualifications are:~~

- ~~Bachelors Degree in Medical Technology, Chemistry, Biology, or related natural science or equivalent. Documented experience of 8 years or more in a *Doping Control Laboratory* is equivalent to a Bachelor's degree for this position;~~
- ~~Experience in the analysis of doping materials in biological fluids;~~
- ~~Experience in the use of relevant analytical techniques such as chromatography, immunoassay, and mass spectrometric techniques.~~

1.5.2.6 ~~Supervisory personnel shall have a thorough understanding of the quality control procedures including, the review, interpretation and reporting of test results, maintenance of Laboratory Internal Chain of Custody and proper remedial action to be taken in response to analytical problems. The qualifications for supervisor are:~~

- ~~Bachelor's Degree in Medical Technology, Chemistry, Biology, or related natural science or equivalent. Documented experience of 5 years or more in a *Doping Control Laboratory* is equivalent to a Bachelor's degree for this position;~~
- ~~Experience in relevant Analytical Testing including the analysis of *Prohibited Substances* in biological material;~~
- ~~Experience in the use of analytical techniques such as chromatography, immunoassay, and mass spectrometric techniques;~~
- ~~Ability to ensure compliance with quality management systems and quality assurance processes.~~

1.5.3 ~~Accommodation and environmental conditions~~

1.5.3.1 ~~Environmental Control~~

1.5.3.1.1 ~~Maintaining appropriate electrical services~~

~~1.5.3.1.1.1—The Laboratory shall ensure that adequate electrical service is available so that there is no compromise of stored data.~~

~~• All Laboratory instrumentation and equipment critical to Laboratory operations should be supported in such a way that service is not likely to be interrupted.~~

~~• The Laboratory shall have policies in place to ensure the integrity of refrigerated and/or frozen stored Samples in the event of an electrical failure.~~

~~5.1.0.1.15.1.1.1—The Laboratory shall have a written safety policy and compliance with Laboratory safety policies shall be enforced.~~

~~1.5.3.1.2—The storage and handling of controlled substances shall follow a risk assessment and comply with applicable national legislation.~~

~~1.5.3.2—Security of the facility~~

~~1.5.3.2.1—The Laboratory shall have a policy for the security of its facilities, equipment and system against unauthorized access which may include a threat and risk assessment by expert(s) in the relevant field.~~

~~1.5.3.2.2—Three levels of access shall be considered in the quality manual or threat assessment plan:~~

- ~~• Reception zone: An initial point of control beyond which unauthorized individuals shall be escorted by laboratory personnel;~~
- ~~• Common operational zones;~~
- ~~• Controlled zones: access to these areas should be monitored and records maintained of access by visitors.~~

~~1.5.3.2.3—The Laboratory shall restrict access to controlled zones to only authorized persons. A staff member should be assigned as the security officer who has overall knowledge and control of the security system.~~

~~1.5.3.2.4—Unauthorized Persons shall be escorted within Controlled Zones. A temporary authorization may be issued to individuals requiring access to the Controlled Zones such as auditing teams and individuals performing service or repair.~~

~~1.5.3.2.5—The Laboratory should have a separate Controlled Zone for Sample receipt and Aliquot preparation.~~

~~5.1.0.25.1.1.1—Relocation of Laboratory Facilities~~

~~In cases where a Laboratory is to relocate, on a permanent or semi-permanent basis to a new physical space, a report containing the following information shall be provided to WADA no later than three months prior to the relocation:~~

- ~~Description of circumstances for moving Laboratory operations into a new space and anticipated effect on capabilities;~~
- ~~Relocation date(s) including date of closing of existing facility operations and date of opening of future facility operations;~~
 - ~~Date(s) of ISO/IEC 17025 inspection(s) of new facilities (evidence of continued accreditation required when made available by the Accreditation Body);~~
 - ~~New Laboratory contacts and coordinates;~~
 - ~~Assessment of the effect of the relocation to Laboratory client operations.~~

1.5.4—Test methods and method validation

1.5.4.1—Selection of methods

~~Standard methods are generally not available for Doping Control analyses. The Laboratory shall develop, validate and document methods for the detection of substances present on the Prohibited List and for associated Metabolites or Markers or related substances. Note that for many substances, the associated Metabolites are detected, thereby confirming the metabolism and the administration of a Prohibited Substance. The methods shall be selected and validated so they are Fit for purpose.~~

1.5.4.1.1—Non-Threshold Substances

~~Laboratories are not required to quantify or report a concentration for Non-Threshold Substances.~~

~~The Laboratory shall develop, as part of the method validation process, acceptable standards for identification of Prohibited Substances using Reference Materials and in the absence of available Reference Materials, Reference Collections may be used (see the Technical Document on Identification Criteria).~~

~~The Laboratory shall estimate the limit of detection and demonstrate the ability to successfully detect each Non-Threshold Substance or its representative Metabolite(s) or Marker(s) at 50% of the Minimum Required Performance Levels (see the TD MRPL for detection and identification of Non-Threshold Substances). A Reference Collection may be used for identification and in such cases an estimate of the detection capability for the method may be provided by assessing a representative substance from the same class of Prohibited Substances with similar chemical structure.~~

1.5.4.1.2 ~~Threshold Substances~~

The ~~Laboratory~~ shall develop quantitative methods that are ~~Fit for purpose~~.

For endogenous ~~Threshold Substances~~, the ~~Athlete's Sample~~ will be deemed to contain a ~~Prohibited Substance~~ and the ~~Laboratory~~ will report an ~~Adverse Analytical Finding~~ if, based on any reliable analytical method the ~~Laboratory~~ can show that the ~~Prohibited Substance~~ is of exogenous origin.

1.5.4.2 ~~Validation of methods~~

1.5.4.2.1 ~~Confirmation methods for Non-Threshold Substances shall be validated. Factors to be investigated in the validation procedure to demonstrate that a method is Fit for purpose include but are not limited to:~~

- ~~Specificity. The ability of the assay to detect only the substance of interest shall be determined and documented. The assay shall be able to discriminate between compounds of closely related structures;~~
- ~~Limit of Detection (LOD) shall be determined at least to 50% of the relevant MRPL for each Non-Threshold Substance or its representative Metabolite(s) or Marker(s) using the relevant Reference Material, when available (see the Technical Document on Minimum Required Performance Levels);~~
- ~~Identification capability. Since the results for Non-Threshold Substances are qualitative, not quantitative, the Laboratory should establish criteria for the Confirmation Procedures ensuring the identification (in compliance with the Technical Document on Identification Criteria) of each Non-Threshold Substance or its representative Metabolite(s) or Marker(s), for which a Reference Material is available, at the MRPL;~~
- ~~Robustness. The method shall be determined to produce similar results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results shall be controlled;~~
- ~~Carryover. The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis shall be determined and implemented;~~
- ~~Matrix interferences. The method should avoid interference in the detection of Prohibited Substances or their Metabolites or Markers by components of the Sample matrix;~~
- ~~Standards. Reference Materials should be used for identification, if available. If there is no reference standard available, the use of data or Sample from a validated Reference Collection is acceptable. If the Laboratory can show by the analysis of Reference Material (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 or microsomes) the ability to detect a particular substance, this shall be regarded as sufficient evidence to confirm identity.

This Article applies only to the validation of Laboratory methods, and not to the review of the analytical results for any *Athlete Sample(s)*.

1.5.4.2.2 Confirmation methods for Threshold Substances shall be validated. Factors to be investigated to demonstrate that a method is Fit for purpose include but are not limited to:

- Specificity. The ability of the assay to detect only the substance of interest shall be determined and documented. The assay shall be able to discriminate between compounds of closely related structures;
- Intermediate Precision. The method shall allow for the reliable repetition of the results at different times and with different operators performing the assay. Intermediate Precision at the threshold shall be recorded;
- Robustness. The method shall be determined to produce the similar results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results shall be controlled;
- Carryover. The conditions required to eliminate carryover of the substance of interest from *Sample* to *Sample* during processing or instrumental analysis shall be determined and implemented;
- Matrix interferences. The method shall limit interference in the measurement of the amount of *Prohibited Substances* or their *Metabolites* or *Markers* by components of the *Sample* matrix;
- Standards. Reference Materials should be used for quantification, if available;
- Limit of quantification (LOQ). The Laboratory shall demonstrate that a threshold method 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 Guideline(s);
- Linearity shall be documented at 50% to 200% of the threshold value, unless otherwise stipulated in a Technical Document or Guideline(s).

This Article applies only to the validation of Laboratory methods, not to the review of the analytical results for any *Athlete Sample(s)*.

1.5.4.2.3 Analytical method validation data (including the estimation of Measurement Uncertainty as described in ISL 5.4.4.3) is assessed in the ISO/IEC 17025 accreditation process for approval of the method for its

inclusion in the Laboratory's ISO scope of accreditation. As such, a Laboratory shall not be required to produce validation data or other evidence of method validation in any legal proceeding.

1.5.4.3 ~~Estimate of Measurement Uncertainty for quantitative analyses~~

1.5.4.3.1 ~~Establishing that a substance exceeds a Threshold.~~

The purpose of reporting (based on the application of Decision Limits which incorporate the maximum acceptable value of the combined standard uncertainty (U_{C-MAX}) of the Laboratory's measurement procedure estimated at the Threshold) is to establish that the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* is present at a concentration and/or ratio of measured analytical values greater than the Threshold with statistical confidence of at least 95%. The method, including selection of standards and controls, and estimation of uncertainty shall be Fit for purpose.

1.5.4.3.1.1 ~~Uncertainty of quantitative results, particularly at the threshold value, shall be addressed during the validation of the assay.~~

1.5.4.3.1.2 ~~Measurement Uncertainty is further addressed in the Technical Document on Decision Limits and relevant guidelines.~~

1.5.4.4 ~~Control of data~~

1.5.4.4.1 ~~Data and computer security~~

1.5.4.4.1.1 ~~All reasonable measures shall be taken to prevent intrusion and copy of data from computer systems.~~

1.5.4.4.1.2 ~~Access to computer terminals, computers, servers or other operating equipment shall be controlled by physical access and by multiple levels of access controlled by passwords or other means of employee recognition and identification. These include, but are not limited to account privileges, user identification codes, disk access, and file access control.~~

1.5.4.4.1.3 ~~The operating software and all files shall be backed up on a regular basis and an updated copy shall be either stored in a fire and water proof environment or kept off site at a secure location.~~

1.5.4.4.1.4 ~~The software shall prevent the changing of results unless there is a system to document the person doing the editing and that editing can be limited to users with proper level of access.~~

~~5.1.0.2.15.1.1.1.1.1 — All data entry, recording of reporting processes and all changes to reported data shall be recorded with an audit trail. This shall include the date and time, retention of original data, reason for the change to original data and the individual performing the task.~~

1.5.5 — Equipment

~~1.5.5.1 — A List of available equipment is to be established and maintained.~~

~~1.5.5.2 — As part of a quality system, the Laboratory shall operate a program for the maintenance and calibration of equipment according to ISO/IEC 17025 Section 5.5.~~

~~1.5.5.3 — General Laboratory equipment (fume hoods, centrifuges, evaporators, etc.) that is not used for making measurements should be maintained by visual examination, safety checks and cleaning as necessary. Calibrations are only required where the setting can significantly change the test result. A maintenance schedule, at least to manufacturer's recommendations or local regulations if available, shall be established for general Laboratory equipment which is used in the test method.~~

~~1.5.5.4 — Equipment or volumetric devices used in measuring shall have periodic performance checks along with servicing, cleaning, and repair.~~

~~1.5.5.5 — Qualified subcontracted vendors may be used to service, maintain, and repair measuring equipment.~~

~~1.5.5.6 — All maintenance, service, and repair of equipment shall be documented.~~

1.5.6 — Measurement traceability

1.5.6.1 — Reference Materials

~~When available, Reference Materials of drug or drug Metabolite(s) traceable to a national standard or certified by a body of recognized status, such as USP, BP, Ph.Eur. or WHO, should be used. At a minimum, an analysis report must be obtained.~~

~~When a Reference Material is not certified, the Laboratory shall verify its identity and purity by comparison with published data or by chemical characterization.~~

~~5.1.0.2.15.1.1.1.1.1 — Reference Collections~~

~~A collection of Sample or isolates may be obtained from a biological matrix following a verifiable administration of an authentic Prohibited Substance or Prohibited Method, providing that the analytical data are sufficient to justify the identity of the relevant chromatographic peak or isolate as a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Prohibited Method.~~

1.5.7—Assuring the quality of analytical results

1.5.7.1—The Laboratory shall participate in the WADA EQAS.

1.5.7.2—The Laboratory shall have in place a quality control system, including the submission of blind quality control samples that challenges the entire scope of the analytical process (i.e., Sample receipt and accessioning through result reporting).

1.5.7.3—Analytical performance shall be monitored by operating quality control schemes appropriate to the type and frequency of testing performed by the Laboratory. The range of quality control activities include, but are not limited to:

- Appropriate positive controls and negative controls shall be included in the same analytical run both for the Initial Testing Procedure and Confirmation Procedure as the Presumptive Adverse Analytical Finding Sample;
- Deuterated or other appropriate internal standard(s) shall be used;
- Comparison of mass spectra or ion ratios from selected ion monitoring (SIM) to a Reference Material or Reference Collection Sample analyzed in the same analytical run;
- Confirmation of the "A" and "B" Samples;
- For Threshold Substances, quality control charts referring to appropriate control limits depending on the analytical method employed (e.g., $\pm 10\%$ of the target value; $\pm 3SD$), should be used;
- The quality control procedures shall be documented by the Laboratory.

~~2.0 Application of ISO/IEC 17025 to the Analysis of Blood Doping Control Samples~~

~~2.1 Introduction and Scope~~

~~This section of the document is intended as an application as described in Annex B.4 (Guidelines for establishing applications for specific fields) of ISO/IEC 17025 to the field of Doping Control. Any aspect of testing or management not specifically discussed in this document 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 WADA accredited laboratory and are therefore determined to be significant in the evaluation and accreditation process.~~

~~This section introduces the specific performance standards for a WADA accredited laboratory. The conduct of 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 main categories of processes:~~

- ~~• Analytical and technical processes;~~
- ~~• Management processes;~~
- ~~• Support processes.~~

~~Wherever possible, the application will follow the format of the ISO/IEC 17025 document. The concepts of the management system, continuous improvement, and customer satisfaction have been included. In some circumstances, measurements of blood parameters may be conducted according to ISO/IEC 15189.~~

~~2.2 Analytical and Technical Processes~~

~~2.2.1 Receipt of Samples~~

~~2.2.1.1 Samples may be received by any method acceptable under the concepts of the International Standard for Testing and Investigations.~~

~~2.2.1.2 The transport container shall first be inspected and any irregularities recorded.~~

~~2.2.1.3 The transfer of the Samples from the courier or other person delivering the Samples shall be documented including at a minimum, the date, the time of receipt, and the name and signature of the Laboratory representative receiving the Sample(s). This information shall be included into the Laboratory Internal Chain of Custody record(s).~~

2.2.2—Handling and retention of *Samples*

2.2.2.1—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.

2.2.2.2—The *Laboratory* shall have *Laboratory Internal Chain of Custody* procedures to maintain control of and accountability for *Samples* from receipt through to final disposition of the *Samples*. The procedures shall incorporate the concepts presented in the applicable WADA Technical Document for *Laboratory Internal Chain of Custody*.

2.2.2.3—The *Laboratory* shall observe and document conditions that exist at the time of receipt that may adversely impact on the integrity of a *Sample*. For example, irregularities noted by the *Laboratory* should include, but are not limited to:

- Sample Tampering* is evident;
- Sample* is not sealed with tamper-resistant device or not sealed upon receipt;
- Sample* is without a collection form (including *Sample* identification code) or a blank form is received with the *Sample*;
- Sample* identification is unacceptable. For example, the number on the bottle does not match the *Sample* identification number on the form;
- Sample* volume is inadequate to perform the requested testing menu;
- Sample* transport conditions are not consistent with preserving the integrity of the *Sample* for anti-doping analysis.

2.2.2.4—The *Laboratory* shall notify and seek instructions from the *Testing Authority* regarding rejection and testing of *Samples* for which irregularities are noted (e.g. a *Sample* sent as whole blood for blood transfusion testing has coagulated). If applicable, any agreement between a *Testing Authority* and *Laboratory* that establishes *Sample* rejection criteria shall be documented.

2.2.2.5—*Samples* for which *Analytical Testing* is to be performed on serum/plasma fraction only (not on cellular components).

Unless otherwise specified in a specific Technical Document or Guidelines, *Samples* should be centrifuged as soon as is practical after *Laboratory* reception to obtain the serum or plasma fraction. When analyzed shortly after centrifugation (within 48 hours), the serum or plasma *Samples* and/or *Aliquots* may be stored refrigerated at approximately 4 degrees Celsius until analysis. For longer term analyses, *Samples* which have been centrifuged shall be frozen according to established protocols and thawed before analysis. In all circumstances, the appropriate steps to ensure the integrity of the *Sample* shall be taken by the *Laboratory*. The *Laboratory* shall retain the "A" and "B" *Samples* with or without *Adverse Analytical Finding(s)* for a minimum

of three months after the Testing Authority receives the final analytical ("A" or "B" Sample) report. The Samples shall be retained frozen under appropriate conditions.

Samples with irregularities shall be held under appropriate conditions for a minimum of three months following the report to the Testing Authority.

After the applicable storage period above, the Laboratory shall do one of the following with the Samples:

- ~~Disposal of the Sample(s).~~
- ~~If the Testing Authority has arranged for storage of the Samples for a period from three months to ten years, the Laboratory shall ensure that the Samples are stored in a secure location under continuous chain of custody.~~
- ~~If consent has been obtained from the Athlete, the Samples may be retained by the Laboratory for research purposes. Samples used for research purposes shall have any means of identification removed or the Sample shall be transferred into an anonymous container such that the contents cannot be traced back to a particular Athlete.~~

If consent has not been obtained from the Athlete, and provided that the Samples are made anonymous, the Samples may be retained by the Laboratory for quality assurance and quality improvement purposes, including but not limited to:

- ~~Improving existing analytical methods;~~
- ~~Developing or evaluating new analytical methods;~~
- ~~Developing reference ranges or Decision Limits or other statistical purposes.~~

Disposal and long term storage of Samples shall be conducted and recorded under the Laboratory Internal Chain of Custody.

2.2.2.6 ~~Samples that consist of whole blood or blood fractions for which tests on cellular components are to be performed.~~

Samples shall be maintained at approximately four degrees Celsius and should be analyzed as soon as practical but within 48 hours. As soon as practicable after Aliquots have been taken for analysis, Samples shall be returned to approximately four degrees Celsius storage. In all circumstances, the appropriate steps to ensure the integrity of the Sample shall be taken by the Laboratory. The Laboratory shall retain the "A" and "B" Samples with or without Adverse Analytical Finding for a minimum of one month after the Testing Authority receives the final analytical ("A" or "B" Sample) report.

~~Samples with irregularities shall be held under appropriate conditions for a minimum of one month following the report to the Testing Authority.~~

~~After the applicable storage period above, the Laboratory shall do one of the following with the Samples:~~

- ~~• Disposal of the Sample(s).~~
- ~~• If the Testing Authority has arranged for storage of the Samples beyond the minimum one month period, the Laboratory shall ensure that the Samples are stored in a secure location under continuous chain of custody.~~
- ~~• Samples used for research purposes shall have any means of identification removed or the Sample shall be transferred into an anonymous container such that the contents cannot be traced back to a particular Athlete.~~

~~If consent has been obtained from the Athlete and provided that the Samples are made anonymous, the Samples may be retained by the Laboratory for research purposes.~~

~~If consent has not been obtained from the Athlete, and provided that the Samples are made anonymous, the Samples may be retained by the Laboratory for quality assurance and quality improvement purposes, including but not limited to:~~

- ~~• Improving existing analytical methods;~~
- ~~• Developing or evaluating new analytical methods;~~
- ~~• Developing reference ranges or Decision Limits or other statistical purposes.~~

~~Disposal and long term storage of Samples shall be conducted and recorded under the Laboratory Internal Chain of Custody.~~

~~2.2.2.7 If the Laboratory has been informed by the Testing Authority that the analysis of a Sample is challenged or disputed, the Sample shall be stored under appropriate conditions and all the records pertaining to the testing of that Sample shall be stored until completion of any challenges.~~

~~2.2.2.8 The Laboratory shall maintain a policy pertaining to retention, release, and disposal of Samples or Aliquots.~~

~~2.2.2.9 The Laboratory shall maintain custody information on the transfer of Samples, or portions thereof to another Laboratory.~~

~~2.2.2.10 In cases where both "A" and "B" Samples have been reported as an Adverse Analytical Finding(s) and no challenge, dispute or longitudinal study is pending, the Laboratory shall either make the Samples available for research or dispose of the Samples. Disposal of Samples shall be conducted and recorded under the Laboratory Internal Chain of Custody.~~

~~2.2.2.11 Long term storage of Samples for Further Analysis:~~

~~The procedures for selection, transport, storage and Further Analysis set forth in Article 5.2.2.12 shall apply unless provided otherwise in an applicable Technical Document or Guidelines.~~

2.2.3—Sampling and preparation of Aliquots for analysis

The sampling and preparation of Aliquots for analysis listed under ISL section 5.2.3 shall apply.

2.2.4—Analytical Testing

2.2.4.1—Blood Initial Testing Procedure

~~The Initial Testing Procedure(s) shall be documented, as part of the Sample (or Sample batch) record, each time it is conducted. Laboratories may apply additional accredited test methods to Samples (beyond the client's requested test menu) if the additional work is conducted at the Laboratory's expense and the relevant Samples have not been identified for long term storage.~~

~~2.2.4.1.1 Unless otherwise approved by WADA after consulting with a Testing Authority, the Initial Testing Procedure(s) shall be capable of detecting the Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method for substances covered by the Prohibited List for which there is a method that is Fit for Purpose. WADA may make specific exceptions to this section for specialized techniques that are not required to be within the scope of accreditation of all Laboratories.~~

~~2.2.4.1.2 The Initial Testing Procedure shall be performed with a Fit for purpose method for the Prohibited Substance or Prohibited Method being tested. A characteristic 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 Procedures can be included as part of longitudinal studies provided that the method is appropriately~~

~~validated.~~

~~2.2.4.1.3 All batches undergoing the Initial Testing Procedure shall include appropriate negative and positive controls in the same matrix as the Samples being tested.~~

~~2.2.4.1.4 Initial Testing Procedure results are not required to consider the Measurement Uncertainty.~~

~~2.2.4.1.5 Irregularities in the Initial Testing Procedure(s) shall not invalidate an Adverse Analytical Finding when the Confirmation Procedure adequately compensates for such irregularities.~~

~~2.2.4.2 Blood Confirmation Procedure~~

~~Confirmation Procedures shall be documented, as part of the Sample (or Sample batch) record. The objective of the Confirmation Procedure is to accumulate additional information to support the reporting of an Adverse Analytical Finding.~~

~~2.2.4.2.1 "A" Sample confirmation~~

~~2.2.4.2.1.1 A Presumptive Adverse Analytical Finding from an Initial Testing Procedure of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method shall be confirmed using an additional Aliquot(s) taken from the original "A" Sample.~~

~~2.2.4.2.1.2 Affinity Binding Assays applied for the Initial Testing Procedures and Confirmation Procedures shall use antibodies recognizing different epitopes of the macromolecule analyzed, unless a properly validated purification or separation method is incorporated into the confirmation method to eliminate the potential for cross-reactivity prior to the application of "A" confirmation Affinity Binding Assay. The Laboratory shall document, as part of the method validation, the Fitness for Purpose of such purification or separation method.~~

~~In assays which include multiple affinity reagents (such as sandwich immunoassays), only one of the affinity reagents (either applied for capture or detection of the target analyte) used in the Affinity Binding Assays applied for the Initial Testing Procedures and Confirmation Procedures must differ for antigenic epitope specificity. The other affinity reagent may be used in both assays.~~

~~For analytes that are too small to have two independent antigenic epitopes, two different purification methods or two different analytical methods shall be applied.~~

~~Multiplexed Affinity Binding Assays, protein chips, and similar simultaneous multi-analyte testing approaches may be used.~~

~~2.2.4.2.1.3 Antibodies may also be used for specific labelling of cell components and other cellular characteristics. When the purpose of the test is to identify populations of blood constituents, the detection of multiple Markers on the cells as the criteria for an Adverse Analytical Finding replaces the requirement for two antibodies recognizing different antigenic epitopes.~~

~~[Comment: An example is the detection of surface Markers on red blood cells (RBCs) using flow cytometry. The flow cytometer is set up to selectively recognize RBCs. The presence on the RBCs of more than one surface Marker (as determined by antibody labelling) as a criterion for an Adverse Analytical Finding may be used as an alternative to multiple antibodies to the same Marker.]~~

~~2.2.4.2.1.4 The Laboratory shall have a policy to define those circumstances where the Confirmation Procedure of an "A" Sample may be repeated (e.g., batch quality control failure) and the first test result shall be nullified. Each repeat confirmation shall be documented and be completed on a new Aliquot of the "A" Sample.~~

~~2.2.4.2.1.5 If more than one Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method is identified by the Initial Testing Procedures, the Laboratory shall confirm as many of the Presumptive Adverse Analytical Findings as possible. The decision on the prioritization for the confirmation(s) shall be made to give precedent to non-specified substance(s) and the decision should be made in cooperation with the Testing Authority and documented.~~

~~2.2.4.2.1.6 For Threshold Substances, Adverse Analytical Finding or Atypical Finding decisions for the "A" Sample finding shall be based on the mean of the measured analytical values (e.g.) or ratio calculated from the means of measured analytical values (e.g. concentrations, chromatogram peak heights or areas) of three Aliquots. That value shall exceed the value of the relevant Decision Limit as specified in the Technical Document on Decision Limits or applicable Guidelines.~~

~~If insufficient Sample volume exists to analyze three Aliquots, the maximum number of Aliquots that can be prepared should be analyzed. The reporting of Adverse Analytical Findings for Threshold Substances~~

shall be in compliance with the Technical Document on Decision Limits or the applicable Technical Document or Guideline.

~~2.2.4.2.2 — "B" Sample confirmation~~

~~2.2.4.2.2.1 Samples that consist of plasma, serum or other blood fractions for which no tests on cellular components are to be performed: In those cases where confirmation of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method is requested in the "B" Sample, the "B" Sample analysis should occur as soon as possible and should take place no later than seven working days starting the first working day following notification of an "A" Sample Adverse Analytical Finding by the Laboratory.~~

~~Samples that consist of whole blood or blood fractions for which tests on cellular components are to be performed: When required, "B" Sample confirmation in whole blood or blood cellular fraction should take place no later than seven working days starting the first working day following notification of an "A" Sample Adverse Analytical Finding by the Laboratory.~~

~~The Laboratory shall proceed as described above unless informed that the Athlete has waived his/her right to the "B" confirmation analysis and therefore accepts the finding(s) of the "A" confirmation analysis.~~

~~2.2.4.2.2.2 The "B" Sample confirmation shall be performed in the same Laboratory as the "A" Sample confirmation.~~

~~2.2.4.2.2.3 If the "B" Sample confirmation proves negative, the entire test shall be considered negative.~~

~~2.2.4.2.2.4 For exogenous Threshold Substances, the "B" Sample results shall only confirm the "A" Sample identification for the Adverse Analytical Finding to be valid. No quantitation of such Prohibited Substance shall be performed.~~

~~2.2.4.2.2.5 For endogenous Threshold Substances, Adverse Analytical Finding decisions for the "B" Sample finding shall be based on the mean of the measured analytical values (e.g. concentration) or ratio calculated from the means of measured analytical values (e.g. concentrations, chromatogram peak heights or areas) of three Aliquots. That value shall exceed the value of the relevant Threshold as specified in the Technical Document on Decision Limits or the applicable Technical Document or~~

~~Guideline:~~

~~If insufficient *Sample* volume exists to analyze three *Aliquots*, the maximum number of *Aliquots* that can be prepared should be analyzed.~~

~~2.2.4.2.2.6 The *Athlete* and/or his/her representative, a representative of the entity responsible for *Sample* collection or results management, a representative of the *National Olympic Committee*, *National Sport Federation*, *International Federation*, and a translator shall be authorized to attend the "B" confirmation.~~

~~If the *Athlete* declines to be present or the *Athlete's* representative does not respond to the invitation or if the *Athlete* or the *Athlete's* representative continuously claim not to be available on the date of the opening, despite reasonable attempts by the *Laboratory* to accommodate their dates, over a period not to exceed seven working days, the *Testing Authority* or the *Laboratory* shall proceed regardless and appoint an independent witness to verify that the "B" *Sample* container shows no signs of *Tampering* and that the identifying numbers match that on the collection documentation. At a minimum, the *Laboratory* Director or representative and the *Athlete* or his/her representative or the independent witness shall sign *Laboratory* documentation attesting to the above.~~

~~The *Laboratory* Director may limit the number of individuals in *Controlled Zones* of the *Laboratory* based on safety or security considerations.~~

~~The *Laboratory* Director may remove, or have removed by proper authority, any *Athlete* or representative(s) interfering with the testing process. Any behavior resulting in removal shall be reported to the *Testing Authority* and may be considered an anti-doping rule violation in accordance with Article 2.5 of the *Code*, "*Tampering or Attempted Tampering with any part of Doping Control*".~~

~~2.2.4.2.2.7 *Aliquots* taken for "B" Confirmation Procedure shall be taken from the original "B" *Sample*. Refer to urine section 5.2.4.3.2.7.~~

~~2.2.4.2.2.8 If more than one *Prohibited Substance*, *Metabolite(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use of a Prohibited Substance* or *Prohibited Method* has been confirmed in the "*A*" Confirmation Procedure, the *Laboratory* shall confirm as many of the *Adverse Analytical Findings* as possible given the "B" sample volume available. The decision on the prioritization for the confirmation(s) shall be made to give precedent to the substance(s) with the longest potential period~~

~~of *Ineligibility* and the decision should be made in cooperation with the *Testing Authority* and documented.~~

~~2.2.4.2.2.9 The *Laboratory* shall have a policy to define those circumstances when confirmation testing of the "*B*" *Sample* may be repeated (e.g. batch quality control failure) and the first test result shall be nullified. Each repeat confirmation shall be documented and should be performed on a new *Aliquot* of the "*B*" *Sample* and new quality control samples.~~

~~2.2.4.2.2.10 If the "*B*" *Sample* confirmation proves negative, the *Sample* shall be considered negative and the *Testing Authority*, *WADA* and the International Federation notified of the new analytical finding.~~

~~2.2.4.3—Alternative biological matrices~~

~~Any testing results obtained from hair, nails, oral fluid or other biological material shall not be used to counter *Adverse Analytical Findings* from blood.~~

~~2.2.5—Results management~~

~~2.2.5.1—Review of results~~

~~2.2.5.1.1—A minimum of two certifying scientists shall conduct a separate and impartial review of all *Adverse Analytical Findings* before a report is issued. The review process shall be recorded.~~

~~2.2.5.1.2—At a minimum, the review shall include:~~

~~• *Laboratory Internal Chain of Custody* documentation;~~

- ~~• Validity of the analytical initial and confirmatory data and calculations;~~
- ~~• Quality control data;~~
- ~~• Completeness of documentation supporting the reported analytical findings.~~

~~2.2.5.1.3—When an *Adverse Analytical Finding* is rejected, the reason(s) shall be recorded.~~

~~2.2.6—Documentation and reporting~~

~~6.2.6.1—The *Laboratory* shall have documented procedures to ensure that it maintains a coordinated record related to each *Sample* analyzed. In the case of an *Adverse Analytical Finding*, the record shall include the data necessary to support the conclusions reported as set forth in and limited by the Technical Document on Laboratory Document Packages.~~

~~6.2.6.2—Each step of Analytical Testing shall be traceable to the staff member who performed that step.~~

~~6.2.6.3—Significant variance from the written procedure shall be documented as part of the record (e.g., memorandum for the record).~~

~~6.2.6.4—Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record.~~

~~6.2.6.5—Reporting of "A" Sample results should occur within ten working days of receipt of the Sample. The reporting time required for specific Competitions may be substantially less than ten days. The reporting time may be altered by agreement between the Laboratory and the Testing Authority.~~

~~6.2.6.6—A single, distinct Test Report or ADAMS record shall be generated to document the Adverse Analytical Finding(s) of an individual Sample. The Laboratory Test Report shall include, in addition to the items stipulated in ISO/IEC 17025, the following:~~

- ~~• Sample code;~~
- ~~• Laboratory identification number;~~
- ~~• Type of test (Out of Competition/In-Competition);~~
- ~~• Sport and/or discipline;~~
- ~~• Name of Competition and/or client reference code (for example: ADAMS test mission code), if provided by the Testing Authority;~~
- ~~• Date of Collection;~~
- ~~• Date of receipt of Sample;~~
- ~~• Date of report;~~
- ~~• Sex of the Athlete;~~
- ~~• Type of Sample (urine, blood, etc.);~~
- ~~• Test results (for Threshold Substances, in compliance with the Technical Document on Decision Limits or the applicable Technical Document or Guideline);~~
- ~~• The name of the Sample Collection Authority;~~
- ~~• The name of the Testing Authority;~~
- ~~• The name of the Results Management Authority, if provided;~~
- ~~• Signature of authorized individual;~~
- ~~• Other information as specified by the Testing Authority and/or WADA.~~

At a minimum, labelling and information provided by the Laboratory related to the type of test, sport/discipline, test results (including comments/opinions) and client to whom the report is addressed shall also be provided in English on the test report.

[Comment: A complete analytical test report generated from ADAMS should be considered to have fulfilled the above requirements and therefore should be regarded as an official test report.]

6.2.6.7 The Laboratory is not required to quantify or report a concentration for an analyte of non threshold *Prohibited Substances* in blood *Samples*. The Laboratory shall report the actual *Prohibited Substance(s)*, *Metabolite(s)* of the *Prohibited Substance(s)* or *Prohibited Method(s)*, or *Marker(s)* detected in the blood *Sample*. Upon request of the Testing Authority, Results Management Authority or WADA and where the detected level of a *Prohibited Substance* is relevant to the result management of an anti-doping case, the Laboratory should provide an approximate concentration.

For Threshold Substances in blood *Samples*, the Laboratory report shall establish that the *Prohibited Substance(s)* or its *Metabolite(s)* or *Prohibited Method(s)* or *Marker(s)* of a *Prohibited Method* is present at a concentration and/or ratio of measured analytical values greater than the Decision Limit in accordance with the reporting requirements as described in the Technical Document on Decision Limits or the applicable Technical Document(s) or Guidelines.

6.2.6.8 The Laboratory shall qualify the result(s) of the analysis in the Test Report as:

- *Adverse Analytical Finding;*
- *Atypical Finding;*
- In the absence of the above results, a qualification indicating that no *Prohibited Substance(s)* or *Prohibited Method(s)* or their *Metabolite(s)* or *Marker(s)* were detected on the test menu.

6.2.6.9 The Laboratory shall have a policy regarding the provision of opinions and interpretation of data. An opinion or interpretation may be included in the 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.

[Comment: 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, and whether an observed result is consistent with a set of reported conditions.]

~~6.2.6.10—The Laboratory shall report all test results as defined in ISL provision 6.2.6.8 via ADAMS and simultaneously only to the relevant Testing Authority and/or the responsible International Federation and/or to the Major Event Organization (in the case of Major International Events) not using ADAMS. The information provided in ADAMS shall be in compliance to ISL provision 6.2.6.6. In the case where the sport or Event is not associated with an International Federation (e.g., professional leagues, University and college sports) the Laboratory shall report Adverse Analytical Findings to the Testing Authority and to WADA. All reporting shall be in accord with the confidentiality requirements of the Code.~~

~~6.2.6.11—Upon request, the Laboratory shall report in a format specified by WADA, a summary of the results of tests performed. No information that could link an Athlete's identity with an individual result will be included. The report will include a summary of any Samples rejected for Analytical Testing and the reason for the rejection.~~

~~6.2.6.12—The documentation package should be provided by the Laboratory only to the relevant Results Management Authority or WADA upon request and should be provided within ten working days of the request. Laboratory Documentation Packages shall be in compliance with the WADA Technical Document on Laboratory Documentation Packages.~~

~~6.2.6.13—Athlete confidentiality shall be respected by all Laboratories engaged in Doping Control cases.~~

~~6.2.6.13.1—Testing Authority or WADA requests for information shall be made in writing to the Laboratories.~~

~~6.2.6.13.2—Presumptive Adverse Analytical Findings, Adverse Analytical Findings and Atypical Findings shall not be provided by telephone.~~

~~6.2.6.13.3—Information sent by a facsimile is acceptable if the security of the receiving facsimile machine has been verified and procedures are in place to ensure that the facsimile has been transmitted to the correct facsimile number.~~

~~6.2.6.13.4—Unencrypted email is not authorized for any reporting or discussion of Adverse Analytical Findings if the Athlete can be identified or if any information regarding the identity of the Athlete is included.~~

~~6.2.6.13.5—The Laboratory shall also provide any information by WADA in conjunction with the Monitoring Program, as set forth in Article 4.5 of the Code.~~

2.3—Quality Management Processes

The Laboratory management requirements listed under ISL Section 5.3 shall apply.

2.4 — Support Processes

Except as modified below, the Laboratory support requirements listed under ISL Section 5.4 shall apply. Accordingly, numbering below is not consecutive, but instead, only those sections where changes from Section 5.4 have been made are included.

2.4.1 — Test methods and method validation

2.4.1.1 — Selection of methods

~~Standard methods are generally not available for *Doping Control* analyses. The Laboratory shall develop, validate and document methods for the detection of substances present on the *Prohibited List* and for associated *Metabolites* or *Markers* or related substances. Note that for many substances, the associated *Metabolites* are detected, thereby confirming the metabolism and the administration of a *Prohibited Substance*. The methods shall be selected and validated so they are Fit for purpose.~~

~~For Non-Threshold Substances refer to section 5.4.4.1.1.~~

~~For Threshold Substances refer to section 5.4.4.1.2.~~

2.4.1.2 — Validation of methods

~~For Non-Threshold Substances refer to section 5.4.4.2.1.~~

~~For Threshold Substances refer to section 5.4.4.2.2.~~

2.4.1.3 — Estimate of uncertainty

~~Uncertainty in establishing that a substance exceeds a threshold (Measurement Uncertainty) shall be addressed by the applicable Technical Document or Guidelines.~~

~~PART THREE: ANNEXES~~

~~ANNEX A – WADA EXTERNAL QUALITY ASSESSMENT SCHEME (EQAS)~~

~~6.0 The~~

WADA External Quality Assessment Scheme (EQAS) is designed to continuously

WADA regularly distributes urine or blood External Quality Assessment Scheme (EQAS) samples to Laboratories and, when applicable, to probationary laboratories. The WADA EQAS is designed to continually monitor the capabilities of the Laboratories and probationary laboratories, to evaluate Laboratory~~their~~ proficiency, and to improve test result uniformity between Laboratories. At the same time EQAS samples are used to assess Laboratory routine analytical capacity and performance, reporting turn-around times and overall compliance with WADA Laboratory standards (e.g. ISL, Technical Documents and Technical Letters), as well as other, non-analytical performance criteria. At the same time, the EQAS also represents, via ~~the~~its educational ~~program~~components, a source of continuous improvement for the effectiveness of the Analytical Testing procedures.

1.0 — WADA External Quality Assessment Scheme

Periodically, urine (or blood) samples are distributed by WADA to Laboratories and probationary laboratories, to be analyzed for the presence or absence of *Prohibited Substances, Metabolites, Markers or Methods*. These samples may be Blind or Double-Blind (in such cases the content is unknown to the Laboratories) as well as Open (also Educational) samples (in such cases the content may be indicated):

Blind and Double-Blind EQAS samples contain selected substances or methods such as those *Prohibited Substances, Metabolite(s) of Prohibited Substances, and Marker(s) of Prohibited Substances and Prohibited Methods* which each Laboratory shall examine, using their routine *Initial Testing Procedures and Confirmation Procedures* to detect and identify the analyte(s) whose presence would result in the reporting of an *Adverse Analytical Finding or Atypical Finding*.

The Laboratory shall not communicate with other Laboratories regarding the identity of substances present in or absent from EQAS samples prior to the submission of EQAS results to WADA by all participating laboratories:

1.1 — Open (Educational) EQAS

The Laboratory may be directed to analyze an EQAS sample for a specific *Prohibited Substance or Prohibited Method or Drug Class*. In general, this approach is used for educational purposes or for data gathering. Results from the Educational EQAS are not evaluated within the point scale for Laboratory performance.

The Laboratory shall report the results of open EQAS samples in a format specified by WADA:

6.1 Types of EQAS

6.1.1 Blind EQAS

The Laboratory will be aware that the sample is an EQAS sample, ~~but since it is delivered by WADA's EQAS sample provider. However, the Laboratory will not know the content of the sample.~~

6.1.2 Double-Blind EQAS

~~The Laboratory will not be aware of the Prohibited Substances or Methods, or their Metabolite(s) or Marker(s) present in the sample that the sample is an EQAS sample since it is delivered by a Testing Authority and is indistinguishable from routine Samples.~~

~~The Laboratory shall report the results of blind EQAS samples to WADA in the same manner as specified for routine Samples unless otherwise notified by WADA. For some EQAS samples or EQAS sample sets, additional information may be requested from the Laboratory.~~

4.2 Double-Blind EQAS

~~The Laboratory receives EQAS samples which are indistinguishable from routine Samples. The EQAS samples may consist of blank or adulterated samples or samples containing Prohibited Substances and Prohibited Methods and Methods and/or their Metabolite(s) or Marker(s), the detection and identification of which would constitute an Adverse Analytical Finding(s) or Atypical Finding(s). These samples may be used to assess turn-around time, compliance with documentation package requirements, and other non-analytical performance criteria as well as Laboratory competence in detection and identification of Prohibited Substances or Prohibited Methods, Metabolite(s) of Prohibited Substances, and Marker(s) of Prohibited Substances or Prohibited Methods.~~

External Quality Assessment Scheme 6.1.3 Educational EQAS

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.

As part of the educational EQAS, WADA 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.

WADA may require the successful participation of Laboratories in an educational EQAS for WADA-specific Analytical Testing Procedures in order for Laboratories to seek an extension of the Laboratory's Scope of ISO/IEC 17025 Accreditation by an Accreditation Body (see ISL Art. 4.4.2.2) before the subsequent application of the Analytical Testing Procedure to the routine analysis of Samples.

6.4.2 EQAS Sample Number and Composition

6.2.1 Number of EQAS Samples

The actual composition and number of ~~the~~ EQAS samples supplied to different Laboratories ~~in a particular EQAS round~~ may vary ~~but, however~~, within any ~~annual period~~ calendar year, all Laboratories participating in the EQAS are expected to have analyzed the ~~same~~ minimum total number of EQAS samples.

Each year, the EQAS Samples ~~Void~~ program will consist of ~~Prohibited~~:

- At least fifteen (15) blind EQAS samples, distributed by WADA in multiple rounds;
- At least five (5) double-blind EQAS samples distributed by various Testing Authorities in several rounds;
- At least three (3) of the above EQAS samples will contain Threshold ~~Substances or Methods~~.

6.2.1.1 As part of WADA's Laboratory monitoring activities, and with the main purpose of assisting Laboratories ~~in their~~ Metabolite(s) ~~continuous improvement of performance~~, WADA may increase the number of annual EQAS samples (mainly for educational purposes) for certain Laboratories, according, but not limited, to the following criteria:

- Monitoring the effectiveness of corrective action implementation after questionable or unsatisfactory performance in WADA EQAS or ~~Marker~~ in routine Analytical Testing;
- Substantiated intelligence information received by WADA indicating questionable or unsatisfactory Laboratory performance;
- Laboratories which do not receive enough Samples (< 100 annual Samples) to be analyzed with specific Analytical Testing Procedure(s), which are not part of the Laboratory's routine Analytical Testing menu;
- As part of WADA Laboratory on-site assessments.

6.2.2 Composition of EQAS Samples

EQAS samples may or may not contain Prohibited Substance(s) ~~(blank samples)~~ and/or Metabolite(s) of Prohibited Substance(s) and/or Marker(s) of Prohibited Substance(s) or Prohibited Method(s). Laboratories shall analyze these samples using their routine Initial Testing Procedures and Confirmation Procedures.

6.2.2.1 Blank EQAS Samples

Blank EQAS samples do not contain *Prohibited Substances* or their Metabolite(s) ~~Metabolites~~ or Marker(s) ~~Markers~~ of *Prohibited Substances* ~~and/or~~ *Prohibited Methods*.

6.2.2.2 Adulterated EQAS ~~samples~~ 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~~ 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).

6.2.2.3 EQAS Samples Containing Prohibited Substances, Substance(s), their Metabolite(s) or Marker(s), or the Marker(s) of Prohibited Methods/Method(s)

1.2.1 EQAS sample composition

The concentration(s) of selected ~~analyte~~ Analyte(s) are those that may be ~~expected~~ encountered in the urine or blood ~~after Use of drug users Prohibited Substance(s) or Prohibited Method(s)~~. For some ~~analytes~~ Analytes, the EQAS sample ~~composition may consist of~~ contain the parent ~~drug~~ Prohibited Substance and/or ~~majority~~ Metabolite(s) and/or its Marker(s).

EQAS samples may be spiked with Prohibited Substances, Substance(s) and/or their Metabolite(s) or Marker(s) and/or may but would be preferably prepared from controlled administration studies. The EQAS sample composition shall reflect as closely as possible the expected target Analyte Metabolite pattern and concentrations usually found in Samples ⁵⁸.

1.2.2 Individual EQAS sample content of Prohibited Substance(s) or Method(s), or Metabolite(s) or Marker(s)

An EQAS sample may contain more than one Prohibited Substance, Metabolite(s), or Marker(s) of a Prohibited Substance or Prohibited Method. It ~~is possible that the sample will may also~~ contain multiple Metabolites or Markers of a single ~~substance~~ Prohibited Substance or Markers of a Prohibited Method, which would represent the presence of a single Prohibited Substance. ~~All Metabolites detected should be reported according to the Laboratory's standard operating procedures (e.g., test report, ADAMS). WADA may also require Laboratories to report the results of EQAS samples in other formats, or the Use of a single Prohibited Method.~~

6.2.2.4 Blood EQAS Samples for the analysis of ABP blood Markers

These EQAS samples are distributed to Laboratories and WADA-Approved Laboratories for the ABP on a regular basis (e.g. monthly) with the purpose of evaluating their proficiency in the analysis and reporting of the blood Markers that constitute the hematological module of the ABP.

⁵⁸ To the extent possible (in consideration, for example, of ethical constraints, availability of the pharmaceutical grade substance, etc.), double-blind EQAS samples containing Prohibited Substance(s) and/or Metabolite(s) of Prohibited Substance(s) and/or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) should be prepared from controlled administration studies.

6.2.2.5 For Non-Threshold Substances, the concentration in the EQAS sample will be guided by, but not limited to, one of the following criteria:

- ~~The Concentrations of the Prohibited Substance and/or its major Metabolite(s) will normally be present in quantities or Marker(s) equal to or greater than the Minimum Required Performance Level (MRPL) as applicable. The Laboratory shall report the Prohibited Substance. Results will be evaluated as per section 3.3.5. MRPL (refer to TD MRPL):~~
- ~~The Concentrations of the Prohibited Substance and/or its major Metabolite(s) may be present in quantities or Marker(s) between 50% of the MRPL and the relevant MRPL as applicable. The Laboratory shall report only to Non-Threshold Substances prohibited at all times and with no reporting limits, as per TD MRPL):~~
- ~~Non-Threshold Substances with reporting limits as stated in the TD MRPL (e.g. substances prohibited In-Competition only), will normally be present in estimated concentrations greater than 120% of the applicable reporting limit:~~
 - ~~Concentrations of the Prohibited Substance and/or its Metabolite(s) if identified at a concentration greater than 50% of the MRPL. Between 50% of the MRPL and the relevant MRPL as applicable, the results shall not be evaluated for the purposes of the EQAS point system, however WADA may require an investigation and report.~~
- ~~The Prohibited Substance and/or its major Metabolite(s) may be present or Marker(s) below 50% of the applicable MRPL (for Non-Threshold Substances prohibited at all times with no reporting limits, for educational purposes. In this case, the Laboratory should report their finding(s) if the analyses are compliant with their Standard Operating Procedures, the ISL and relevant Technical Documents. The results shall not be evaluated for the purposes of the EQAS point system):~~
- ~~In some special cases, the Laboratory may be directed to analyze the sample for a particular Prohibited Substance as part of an educational challenge and the results shall not be evaluated for the purposes of the EQAS point system.~~

6.2.2.6 For Threshold Substances, the concentration in the EQAS sample will be guided by, but not limited to, one of the following criteria:

- ~~Above Greater than 50% of the Decision Limit Threshold as determined by established in the relevant Technical Document on Decision Limits(s) or relevant Laboratory Guidelines;~~
- ~~Between At less than 50% of the Threshold and the relevant Decision Limit for special purposes (e.g. estimation of maximum allowed u_e)~~
- ~~those exogenous Threshold Substances specified in the TD DL whose presence shall evaluated as per section 3.3.5~~
- ~~Exceptions may include the reporting of Threshold Substances below the Decision Limit be reported if required by the ISL or applicable Technical Documents (e.g. detection~~

~~of Threshold Substances at sub-threshold levels detected in the presence of diuretics or masking agents).~~

~~These concentrations and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use.~~

2.0 — Evaluation of External Quality Assessment Scheme

Overall and individual round Laboratory EQAS performance will be assessed in accordance with the point system table in section 3.3.5 of this Annex.

2.1 — Evaluation of EQAS Samples Containing Non Threshold Substances

~~When a qualitative determination has been reported, the result will be judged to have properly reported the presence or absence of an *Adverse* 6.2.2.7 Laboratories shall determine the *Markers* of the "steroid profile" in all urine EQAS samples (unless specifically not required in an educational EQAS sample).~~

Laboratory Analytical Finding as intended in the preparation of the EQAS sample.

- ~~• The results of any *Prohibited Substance* and/or its *Metabolite(s)* above the MRPL shall be considered for evaluation as per point system table in section 3.3.5.~~
- ~~• The results of any *Prohibited Substance* and/or its *Metabolite(s)* between 50% of the MRPL and the MRPL shall not be considered for evaluation for the purposes of the Testing Procedures Used in EQAS point system.~~
- ~~• For those substances for which the chirality of a substance may affect the sanction given to an *Athlete*, failure to correctly report the chiral species (e.g., methamphetamine-(d) or levmetamfetamine) will be deemed as a false negative.~~

2.2 — Evaluation of EQAS Samples Containing Threshold Substances

~~When a quantitative determination has been reported, the results can be scored (z-score) based on the nominal or consensus value of the sample analyzed and a target standard deviation which may be set either by the group results or according to the expected precision of the measurement. The z score is calculated using the equation:~~

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

~~Where \bar{x} is the measurement result reported by the participating laboratory.~~

~~\hat{x} is the assigned value.~~

~~δ is the target value for standard deviation.~~

~~The target relative standard deviation will be set in such a way that:~~

- An absolute z-score between zero (0) and two (2.0), inclusive, is deemed **satisfactory** performance;
- An absolute z-score between greater than two (2.0) to less than three (3.0) is deemed to be **questionable** performance;
- An absolute z-score equal to or greater than three (3.0), inclusive, is deemed to be **unsatisfactory** performance.

In the EQAS, the reported concentration from the Confirmation Procedure is scored; therefore the concentration of Threshold Substances shall be reported when the measured mean value is greater than or equal to 50% of the Threshold concentration or ratio.

Concentrations of Threshold Substances (or Metabolites) determined by WADA to be present below the Decision Limit in the EQAS samples shall not be considered for the purposes of the EQAS evaluation unless the reporting of the substance below the Decision Limit is required by the ISL or applicable Technical Documents (e.g. detection of a Threshold Substance in the presence of a diuretic or masking agent).

2.3 Accreditation Maintenance and Laboratory Evaluation

Laboratories shall be challenged with at least 20 EQAS samples each year distributed in multiple rounds of which at least two will include Double-Blind samples. Each year at least three samples will contain Threshold Substances. Blank samples may be included.

The purpose of the EQAS program is to ensure that all of the Laboratories maintain proficiency of their testing methods. Contact between Laboratories regarding any aspect of EQAS testing and EQAS results prior to reporting to WADA will be considered an attempt to circumvent the system. Engaging in such discussions may subject the Laboratories involved to disciplinary action.

6.26.3 Methods utilized in EQAS

All procedures associated with the handling and testing Analytical Testing of the EQAS samples by the Laboratory are ~~to the greatest extent possible,~~ to be ~~carried out~~ conducted in a manner ~~identical~~ similar to that applied to routine Laboratory Samples, unless otherwise specified by WADA. No effort ~~should~~ 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 ~~methods or procedures~~ Fit-for-Purpose Analytical Testing Procedures described in the ~~standard operating procedures and included in the~~ Laboratory's scope of accreditation SOPs are to be employed in the analysis of EQAS samples (~~i.e.~~ using the ~~methods and procedures~~ Analytical Testing Procedures applied in routine ~~analysis~~ Analytical Testing).

~~2.3.1 False Adverse Analytical Finding result~~

~~A false Adverse Analytical Finding result is not acceptable in any Blind and Double Blind EQAS sample. The following procedures are to be followed when faced with such a situation:~~

- ~~• The Laboratory will be informed by WADA of a false Adverse Analytical Finding as soon as possible;~~
- ~~• The Laboratory is to provide WADA with a satisfactory root cause analysis report including the reason(s) for the error within five calendar days (unless informed otherwise by WADA). Supporting documentation shall be provided such as all quality control data from the batch of EQAS or routine Samples that included the false Adverse Analytical Finding sample (particularly if the error is deemed to be technical/scientific);~~

6.4 WADA Reporting of EQAS results

The purpose of the EQAS program is to ensure that all Laboratories maintain proficiency in the performance of their Analytical Testing Procedures and report the results to WADA and the Testing Authority in a timely manner.

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 WADA. This prohibition also applies to Laboratory requests for second opinions, which shall not be requested for blind EQAS samples.

Contact between Laboratories regarding any aspect of blind EQAS analysis (including the results obtained) prior to reporting by all Laboratories to WADA will be considered an attempt to circumvent the quality assessment. Engaging in such discussions will subject the Laboratories involved to disciplinary procedures, which may lead to Suspension or Revocation of WADA accreditation.

For double-blind EQAS samples, which are indistinguishable from routine Samples, consultation between Laboratories before reporting such EQAS results to WADA may occur. However, such consultation shall not involve identifying the sample as a WADA double-blind EQAS sample (in cases when, for any reason, the Laboratory identifies the EQAS nature of the sample).

6.4.1 Reporting Blind EQAS Results

The Laboratory shall report the results of blind EQAS samples to WADA in ADAMS in the same manner as specified for routine Samples (see ISL Art. 5.3.5.2.6) unless otherwise notified by WADA. For some blind EQAS samples or sample sets, additional information may be requested from the Laboratory (e.g. LODs, LOQs, MU estimations, etc.).

The results of the blind EQAS shall be submitted to WADA on or before the specified date unless an extension is granted by WADA for valid reasons. For a failure to report results of blind EQAS samples within the established deadline, without prior approval by WADA, the Laboratory shall receive two (2)

penalty points, and an additional two (2) penalty points per week beyond the applicable deadline (refer to the ISL Points System Table in Art. 7.3).

6.4.2 Reporting Double-Blind EQAS Results

The Laboratory shall report the results of double-blind EQAS samples in ADAMS as per ISL Art. 5.3.5.2.6.

Reporting of results should occur within fifteen (15) working days of receipt of the samples, unless an extension has been agreed with the Testing Authority after the Laboratory has provided the Testing Authority with a valid reason for the delay in the reporting of the results.

Subject to an extension of the above deadline by agreement or otherwise, or to a request based on justified grounds, as determined by WADA, failure to report results of double-blind EQAS samples in ADAMS within thirty (30) calendar days of receipt of the samples, shall carry two (2) penalty points and an additional two (2) penalty points per week beyond the applicable deadline (refer to the ISL Points System Table in Art. 7.3).

6.4.3 Reporting Educational EQAS Results

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 WADA. Results received after the deadline will not be included in the assessment of EQAS results nor in the subsequent educational EQAS report.

6.4.4 Reporting Results for EQAS Samples Containing Non-Threshold Substance

6.4.4.1 Unless otherwise specified by WADA (for example, for 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 the TD IDCR, including the *Prohibited Substance(s)* (i.e. 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)*. WADA may also require that the Laboratory report the estimated concentrations of the confirmed Analyte(s).

6.4.4.2 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.

6.4.5 Reporting Results for EQAS Samples Containing Threshold Substances

6.4.5.1 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.

Unless otherwise specified by WADA (for example, for educational purposes), this provision does not apply to EQAS samples containing those exogenous Threshold Substances specified in the TD DL

whose presence shall be reported, without the need for quantitative confirmation, if detected in the presence of diuretics or masking agents.

6.4.5.2 For double-blind EQAS samples, the Laboratory shall report the quantitative results in ADAMS as done for routine *Samples*, in accordance with the relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines.

7.0 Evaluation of Laboratory EQAS and Routine Analytical Testing Performance

The WADA system of Laboratory EQAS and routine Analytical Testing performance (see ISL Points Scale Table in ISL Art. 7.3 below) has been developed by the WADA LabEG with the objective of setting a transparent and balanced procedure for evaluation of Laboratory and probationary laboratory operations. It is based on the principle of proportionality and is focused on improving Laboratory's Analytical Testing capabilities and, in the case of probationary laboratories, their readiness for obtaining WADA accreditation. It is ultimately aimed at maintaining the confidence in and strengthening of the anti-doping Laboratory system to benefit clean *Athletes*.

7.1 Evaluation of EQAS Results

Satisfactory EQAS performance in single EQAS rounds ⁵⁹ and over a consecutive 12-month period ⁶⁰ is necessary for maintaining WADA accreditation.

Unsatisfactory performance in an educational EQAS for a new or WADA-specific ⁶¹ Analytical Testing Procedure may prevent the Laboratory from seeking an extension of the Laboratory's Scope of ISO/IEC 17025 Accreditation for the Analytical Testing Procedure and from its application in routine Analytical Testing (see ISL Art. 4.4.2.2). The Laboratory may only apply the newly WADA-approved method or procedure for routine *Sample* analysis when it properly corrects the deficiencies identified in the educational EQAS (as determined by WADA) and the method is included in the Laboratory's Scope of ISO/IEC 17025 Accreditation.

⁵⁹ An EQAS Round is a distribution of EQAS sample(s) to the Laboratories and the probationary laboratories for Analytical Testing as defined by WADA.

⁶⁰ The 12-month period to account for the total number of penalty points accumulated by a Laboratory or probationary laboratory according to the ISL Points Scale Table is defined as the most recent consecutive 12-month interval starting either from the date that the Laboratory or the probationary laboratory reported the result (EQAS or routine Analytical Testing, as applicable) in ADAMS or from the date that the Laboratory or probationary laboratory is informed, in writing, of the assigned penalty points total by WADA, whichever is more favorable to the Laboratory or the probationary laboratory. Any assigned penalty points will expire after a 12-month period; however, the total number of penalty points within any consecutive 12-month period shall not reach the maximum allowed number of penalty points established in the ISL Points Scale Table.

⁶¹ Some Analytical Testing Procedures are not eligible for a Flexible Scope of ISO/IEC 17025 Accreditation and require specific WADA approval before the Laboratory can apply the procedure to the analysis of *Samples*. WADA approval will be based on its assessment of the Fitness-for-Purpose of the Analytical Testing Procedure, validation by the Laboratory, and the successful Laboratory participation in an inter-laboratory collaborative study or WADA EQAS round. WADA will communicate which Analytical Testing Procedures fall into this category to the Laboratories and to the Accreditation Bodies (see ISL Article 4.4.2.2).

7.1.1 EQAS Samples Containing Non-Threshold Substances

7.1.1.1 When a qualitative determination of a Non-Threshold Substance has been reported, the Laboratory result will be evaluated on the basis of the correct reporting of the finding (e.g. *Adverse Analytical Finding*, *Negative Finding*) as intended in the preparation of the EQAS sample.

7.1.1.2 The results for any Non-Threshold Substance and/or its *Metabolite(s)* and/or *Marker(s)* at concentrations greater than the MRPL (or exceeding 120% of the reporting limit, when applicable) shall be evaluated in accordance with the ISL Points Scale Table.

7.1.1.3 The results for any Non-Threshold Substance and/or its *Metabolite(s)* and/or *Marker(s)* at concentrations between 50% of the MRPL and the MRPL (or less than 120% of the reporting limit, when applicable) shall not be considered for evaluation for the purposes of the EQAS points system. However, WADA may require an internal investigation and Corrective Action Report from the Laboratory.

7.1.1.4 The results for any Non-Threshold Substance and/or its *Metabolite(s)* and/or *Marker(s)* at concentrations below 50% of the applicable MRPL in an EQAS sample shall not be evaluated for the purposes of the EQAS points system. Nonetheless, the Laboratory should report their finding(s) if the analyses are compliant with its validation data, SOPs, the ISL 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.

7.1.2 EQAS Samples Containing Threshold Substances

7.1.2.1 For EQAS samples containing Threshold Substances at levels greater than 50% of the Threshold, the quantitative determination will be statistically evaluated to determine the compatibility of the reported result with the assigned value (reference, nominal or consensus value, as applicable) through e.g. z-score, degree of equivalence analysis. Results shall be evaluated as per the ISL Points Scale Table ⁶².

This provision does not apply to the reporting of results for certain exogenous Threshold Substances, identified in the TD DL, if detected in the presence of diuretics or masking agents. In such cases, the detection and identification of the exogenous Threshold Substance shall be reported in accordance with the TD DL. The failure to report the presence of the Threshold Substance(s), as applicable, will be considered as a False Negative Finding.

⁶² 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 Decision Limit, is not considered as a False Negative Finding or False *Adverse Analytical Finding*, respectively, if the absolute z-score (truncated to two (2) significant figures) for the Laboratory quantitative result is < 3.0 [see footnote 73].

A Laboratory is to achieve a satisfactory statistical evaluation of quantitative results reported based on the mean of three (3) replicate determinations. The overall evaluation of the quantitative performance is based on the criteria indicated in the effective version of the TD DL or other relevant Technical Document, Technical Letter or Laboratory Guidelines.

7.1.2.2 Unsatisfactory Quantitative Result (absolute z-score ≥ 3) ⁶³

The Laboratory shall provide WADA with a satisfactory Corrective Action Report ⁶⁴ for an unsatisfactory quantitative result. The Corrective Action Report shall be submitted within ten (10) working days of receiving a written notification about the unsatisfactory result from WADA. Failure to submit a satisfactory Correction Action Report or the late submission of the Correction Action Report without prior approval by WADA shall result in the imposition of further penalty points in accordance with the ISL Points Scale Table.

7.1.2.3 Questionable Quantitative Result (absolute z-score > 2 and < 3)

The Laboratory shall perform an internal investigation to determine the cause(s) of the questionable result and implement appropriate corrective measures to resolve them.

7.2 Evaluation of Laboratory Performance

⁶³ The z-score is calculated according to the following formula and truncated to two (2) significant figures:

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

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).

⁶⁴ A Corrective Action Report will be considered as satisfactory when it meets all of the following criteria, as determined by the LabEG:

- 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);
- Leads to the documented implementation of effective corrective action(s) to solve the problem; and
- Leads to the documented implementation of appropriate preventive actions, if applicable, to minimize the risk of recurrence of the problem.

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.

7.2.1 False Adverse Analytical Finding

7.2.1.1 A False Adverse Analytical Finding is not acceptable for any blind or double-blind EQAS sample or during the course of routine Analytical Testing conducted by a Laboratory.

7.2.1.2 False Adverse Analytical Finding during routine Analytical Testing

If the Laboratory discovers that it reported a False Adverse Analytical Finding during routine Analytical Testing, the Laboratory shall inform WADA immediately.

When the False Adverse Analytical Finding is identified by WADA, based on information received from a Testing Authority, a Results Management Authority, through WADA's own results management activities or through any other means, WADA shall inform the Laboratory immediately.

In either case, the Laboratory shall cease all Analytical Testing activities applied to the affected Analytical Testing Procedure(s) and/or Laboratory process(es) (e.g. Sample aliquoting, reporting of results) as soon as it becomes aware or is informed by WADA that a False Adverse Analytical Finding has been reported.

The Laboratory shall provide WADA with a Corrective Action Report, including a Root Cause Analysis of the incorrect results and the corrective action(s) implemented for its rectification, within five (5) working days of informing WADA or been informed by WADA, as applicable, or, in exceptional cases, as otherwise agreed with WADA.

- ~~•—The WADA LabEG shall review the Laboratory's explanation promptly;~~

~~If the error is determined to be a technical or Corrective Action Report within five (5) working days, or within a timeline otherwise determined by WADA, and establish the source of the incorrect result as either a technical/methodological error, the Laboratory shall receive 25 points under the scoring system described in Section 3.3.5 and WADA shall provisionally suspend the Laboratory and subject the Laboratory to an immediate disciplinary process, or a clerical/administrative error.~~

~~The Laboratory may be required to re-test all Samples by WADA to analyze additional EQAS samples and/or to review the analytical results and to re-analyze any relevant and available Samples previously reported as Adverse Analytical Findings by the Laboratory from the time of final resolution of the error back to the time of the last relevant and satisfactory EQAS round during the preceding twelve (12) months (or during a period otherwise determined by WADA) within five (5) working days (unless informed otherwise by WADA) ⁶⁵. Depending on the type/nature of the error that caused~~

⁶⁵ The retrospective review of the analytical results and re-analysis of previous relevant Samples reported as Adverse Analytical Finding(s) is done 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 responsible Testing Authority/Results Management Authority and to WADA. However, the

the ~~false~~False Adverse Analytical Finding, this ~~re-testing~~re-analysis may be limited to one ~~analyte~~Analyte, a class of *Prohibited Substances* or *Prohibited Methods*, or may include any ~~prohibited drug and method~~Prohibited Substance or Prohibited Method. A statement signed by the Laboratory Director shall ~~document~~record this re-~~testing~~analysis. The Laboratory will be required to ~~notify~~inform all ~~of its~~ clients whose Analytical Testing results may have been affected ~~by the error as part of its quality management system~~.

additional False Adverse Analytical Finding(s) will not lead to the accumulation of additional penalty points if produced by the same root cause, as determined by WADA.

7.2.1.2.1 False Adverse Analytical Finding with Consequences being imposed on an Athlete

If the error is determined to be an administrative error (clerical, sample mix-up, etc.), reporting of the False Adverse Analytical Finding has resulted in Consequences being imposed against an Athlete, the Laboratory shall receive ten (20) penalty points under the scoring system described in Section 3.3.5. The Laboratory shall provide a Corrective Action Report describing in accordance with the remedial action(s) taken to avoid ISL Points Scale Table, irrespective of the re-occurrence nature of the particular error in error (technical/methodological or clerical/administrative) that led to the future and evaluate reporting of the impact on routine operations and if deemed necessary False Adverse Analytical Finding.⁶⁶

The LabEG, considering the nature of the error that caused the False Adverse Analytical Finding result, shall make a recommendation to the Chair of the WADA Executive Committee to suspend the Laboratory's WADA accreditation or to impose an Analytical Testing Restriction 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.⁶⁷

7.2.1.2.2 False Adverse Analytical Finding with No Consequences being imposed on an Athlete

- Technical or methodological error

If the Root Cause Analysis investigation performed by the Laboratory shall be required to review and re-analyze previously analyzed Samples during the time required to resolve the identifies the error as technical or methodological, the Laboratory will be initially imposed twenty (20) penalty points in accordance with the ISL Points Scale Table. However, if the Laboratory first informs (i.e. voluntarily self-

⁶⁶ WADA shall inform a Laboratory in writing about the imposition of penalty points, as decided by the LabEG and in accordance with the ISL Points Scale Table. If the final decision regarding the number of penalty points to be imposed is conditional on the evaluation of corrective actions or other follow-up measures (e.g. analysis of further EQAS samples) requested by the LabEG, WADA will only inform the Laboratory about the final number of penalty points imposed at the end of the evaluation process [e.g. 5 penalty points at the end of the evaluation process of a False Negative Finding resolved through the timely implementation of satisfactory corrective action(s)].

⁶⁷ During the period of Suspension, the Laboratory shall follow the instructions provided in ISL Article 4.6.5.2 in regard to Samples in Laboratory's possession at the time of the Suspension. On the other hand, if an Analytical Testing Restriction has been imposed, the Laboratory shall subcontract the affected analyses as provided in ISL Arts. 4.6.5.1 and 5.4.8.

During the Suspension or Analytical Testing Restriction period, WADA will conduct an on-site assessment of the Laboratory's activities, including the analysis of further EQAS samples.

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 WADA, that appropriate steps have been taken to remedy the issue(s) that resulted in the Suspension or Analytical Testing Restriction.

reports) *WADA* of their investigation and discovery of a *False Adverse Analytical Finding*, then the Laboratory will have five (5) points deducted from the twenty (20) penalty points initially assigned.

If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with *WADA*). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, then the Laboratory will be assigned an additional five (5) penalty points and the LabEG shall make a recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's *WADA* accreditation or to impose an Analytical Testing Restriction 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 ⁶⁷.

However, 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 LabEG, the Laboratory will have ten (10) penalty points deducted, in accordance with the ISL Points Scale Table. The Laboratory will be informed by *WADA*, in writing, of the final amount of penalty points assigned in connection with the reporting of the *False Adverse Analytical Finding* ⁶⁶. Provided that the point total accumulated by the Laboratory for a 12-month ⁶⁰ period does not exceed thirty (30) points, the Laboratory will be able to resume Analytical Testing activities following written notification by *WADA*.

- Clerical/Administrative Error ⁶⁸

If the Root Cause Analysis investigation performed by the Laboratory identifies the error as clerical or administrative ~~error~~, the Laboratory will be initially assigned fifteen (15) penalty points in accordance with the ISL Points Scale Table. However, if the Laboratory first informs (*i.e.* voluntarily self-reports) *WADA* of their investigation and discovery of a *False Adverse Analytical Finding*, then the Laboratory will have five (5) points deducted from the fifteen (15) penalty points initially assigned.

If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with *WADA*). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, the Laboratory shall receive an additional ten (10) penalty points in accordance with the ISL Points Scale Table. The LabEG, considering the nature of the clerical/administrative error that caused the *False Adverse Analytical Finding* result, shall make a recommendation to the Chair of the *WADA*

⁶⁸ 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 typo when manually recording an analytical result). The Laboratory shall bear no responsibility for clerical/administrative errors reflected in the Laboratory documentation, which were made, for example, by the Sample Collection Authority or the Testing Authority.

Executive Committee to suspend the Laboratory's WADA accreditation or to impose an Analytical Testing Restriction against the Laboratory, as applicable ⁶⁷.

However, 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 LabEG, the Laboratory will have ten (10) additional penalty points deducted, in accordance with the ISL Points Scale Table. The Laboratory will be informed by WADA, in writing, of the total amount penalty points assigned in connection with the reporting of the False Adverse Analytical Finding ⁶⁶. Provided that the point total accumulated by the Laboratory for a 12-month ⁶⁰ period does not exceed thirty (30) points, the Laboratory will be able to resume Analytical Testing activities following written notification by WADA.

7.2.1.3 False Adverse Analytical Finding for blind or double-blind EQAS sample

In the event that a False Adverse Analytical Finding is reported during the EQAS, WADA will immediately start an investigation to establish if the incorrect result was caused by the EQAS sample provider (blind and double-blind EQAS) or the Testing Authority (double-blind EQAS).

If it is established that the False Adverse Analytical Finding result was caused by an error made by the EQAS sample provider or the Testing Authority, the Laboratory will be informed by WADA and no further action will be required from the Laboratory.

If the WADA investigation indicates that the False Adverse Analytical Finding was caused by an error made by the Laboratory during the Analytical Testing of the EQAS sample(s), the Laboratory shall be informed by WADA as soon as possible. However, if the False Adverse Analytical Finding is related to the analysis of a double-blind EQAS sample and the Laboratory first informs (i.e. voluntarily self-reports) WADA of their investigation and discovery of a False Adverse Analytical Finding, this will be taken into consideration when evaluating the Laboratory's performance in accordance with the ISL Points Scale Table (see below).

The Laboratory shall provide WADA with a Corrective Action Report, including a Root Cause Analysis of the incorrect result(s) and corrective action(s) implemented for its rectification, within ten (10) working days of being informed by WADA (unless otherwise indicated by WADA). In addition, the Laboratory may be provisionally suspended—required by WADA to analyze additional EQAS samples and/or to review the 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 WADA) ⁶⁵, within five (5) working days (unless informed otherwise by WADA). Depending on the nature of the error that caused the false Adverse Analytical Finding, this re-analysis may be limited to one Analyte, a class of Prohibited Substances or Prohibited Methods, or may include any Prohibited Substance or Prohibited Method. A statement signed by the Laboratory Director shall record this re-analysis. The Laboratory will be required to inform all of its clients whose Analytical Testing results may have been affected.

2.3.2 False negative result

The WADA LabEG shall review the Laboratory's Corrective Action Report within ten (10) working days, or within a timeline otherwise determined by WADA.

- Technical or methodological error

If the Root Cause Analysis investigation performed by the Laboratory identifies the error as technical or methodological, the Laboratory will be initially imposed twenty (20) penalty points in accordance with the ISL Points Scale Table. However, if the False Adverse Analytical Finding is related to the analysis of a double-blind EQAS sample and the Laboratory first informs (i.e. voluntarily self-reports) WADA of their investigation and discovery of a False Adverse Analytical Finding, then the Laboratory will have five (5) points deducted from the twenty (20) penalty points initially assigned.

If the Laboratory's Corrective Action Report for the technical or methodological error is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with WADA). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, then the Laboratory will be assigned an additional five (5) penalty points and the LabEG shall make a recommendation to the Chair of the WADA Executive Committee to suspend the Laboratory's WADA accreditation or to impose an Analytical Testing Restriction 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 ⁶⁷.

However, if the Laboratory is able to remedy a technical/methodological error through the implementation of satisfactory corrective action(s) in a timely manner, as determined by the LabEG, the Laboratory will have ten (10) penalty points deducted, in accordance with the ISL Points Scale Table. The Laboratory will be informed by WADA, in writing, of the final amount of penalty points assigned in connection with the reporting of the False Adverse Analytical Finding ⁶⁶.

- Clerical/Administrative Error ⁶⁸

If the Root Cause Analysis investigation performed by the Laboratory identifies the error as clerical or administrative, the Laboratory will be initially imposed fifteen (15) penalty points in accordance with the ISL Points Scale Table. However, if the False Adverse Analytical Finding is related to the analysis of a double-blind EQAS sample and the Laboratory first informs (i.e. voluntarily self-reports) WADA of their investigation and discovery of a False Adverse Analytical Finding, then the Laboratory will have five (5) points deducted from the fifteen (15) penalty points initially assigned.

If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with WADA). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, the Laboratory shall receive an additional ten (10) penalty points in accordance with the ISL

Points Scale Table. The LabEG, considering the nature of the clerical/administrative error that caused the *False Adverse Analytical Finding* result, shall make a recommendation to the Chair of the WADA Executive Committee to suspend the Laboratory's WADA accreditation or to impose an Analytical Testing Restriction against the Laboratory, as applicable ⁶⁷.

However, if the Laboratory is able to remedy the clerical or administrative error through the implementation of satisfactory corrective action(s) in a timely manner, as determined by the LabEG, the Laboratory will have ten (10) points deducted, in accordance with the ISL Points Scale Table. Consequently, the Laboratory will be informed by WADA, in writing, of the final amount of penalty points assigned in connection with the reporting of the *False Adverse Analytical Finding* ⁶⁶.

The reporting of any *False Adverse Analytical Finding* Result, irrespective of whether it relates to routine Analytical Testing or the EQAS, or whether or not it results in the Suspension of a Laboratory's WADA accreditation or an Analytical Testing Restriction, may trigger a WADA Laboratory on-site assessment and the requirement that additional EQAS samples be analyzed by the Laboratory.

7.2.2 False Negative Finding

Laboratories failing to identify and/or report a *Prohibited Substance* and/or its *Metabolite(s)* or the *Marker(s)* of a *Prohibited Substance* or a *Prohibited Method* in a Blind EQAS-blind or double-blind EQAS sample or during routine Analytical Testing shall be informed of the False Negative Finding as soon as possible by WADA. ~~The Laboratory shall receive ten points under the scoring system described in Section 3.3.5. The Laboratory must complete and report corrective action acceptable to WADA within 30 days of the date of written notification by WADA (unless informed otherwise by WADA). The Laboratory may otherwise be advised by WADA to take corrective action(s) or to change a corrective action which has previously been reported to WADA. The corrective action reported to and approved by WADA shall be implemented in the routine operation of the Laboratory within 30 days of the completing the corrective action.~~

2.3.3 Threshold Substance result

~~A Laboratory is to achieve satisfactory z-scores for quantitative results reported based on the mean of three independent determinations. The relative standard deviation is to be commensurate with the validation data and the combined standard uncertainty of the procedure should not exceed the maximum permitted in the Technical Document on Decision Limits or relevant Guideline. To report an *Adverse Analytical Finding*, the mean result must be above the corresponding Decision Limit. Laboratories shall receive either five points for a questionable result or ten points for an unsatisfactory result under the scoring system described in Section 3.3.5. Appropriate corrective action shall be taken to remedy any unsatisfactory z-score and the corrective action reported to WADA within 30 days of written notification of unsatisfactory performance.~~

WADA will immediately start an investigation to establish whether the False Negative Finding was the result of the Laboratory's Analytical Testing process.

If WADA's investigation determines that the False Negative Finding occurred due to mistake(s) related to the Laboratory's Analytical Testing process, the Laboratory will be initially imposed ten (10) penalty points in accordance with the ISL Points Scale Table. However, if the False Negative Finding is related to the analysis of a routine Sample or a double-blind EQAS sample and the Laboratory first informs (i.e. voluntarily self-reports) WADA of their investigation and discovery of a False Negative Finding, then the Laboratory will have five (5) points deducted from the ten (10) penalty points initially assigned.

The Laboratory shall provide WADA with a Corrective Action Report within ten (10) working days (unless otherwise indicated by WADA).

The LabEG shall review the Laboratory's Corrective Action Report within ten (10) working days, or within a timeline otherwise determined by WADA, and take the following steps, where appropriate:

- If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with WADA). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, the Laboratory shall receive an additional five (5) penalty points in accordance with the ISL Points Scale Table. In addition, WADA will request the Laboratory to analyze additional (blind and/or double-blind) EQAS sample(s). Depending on the nature of the error that caused the 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.

The Laboratory shall report correct results for the analysis of all EQAS samples. In addition, the Laboratory shall implement satisfactory corrective action(s) (as determined by WADA) which ensures that the cause(s) of the nonconformity is eliminated, thus avoiding repetition of the mistake in the future. Failure by the Laboratory to report correct results for the additional EQAS sample(s) will incur the imposition of additional penalty points in accordance with the ISL Points Scale Table. The LabEG, considering the nature of the error that caused the False Negative Finding, shall make a recommendation to the Chair of the WADA Executive Committee to suspend the Laboratory's WADA accreditation or to impose an Analytical Testing Restriction against the Laboratory, as applicable ⁶⁷.

- However, if the Laboratory is able to remedy the issue(s) that led to the reporting of the False Negative Finding, through the implementation of satisfactory corrective actions in a timely manner, as determined by the LabEG, five (5) penalty points initially imposed will be deducted, in accordance with the ISL Points Scale Table. Consequently, the Laboratory will be informed by WADA, in writing, of the final amount of penalty points assigned in connection with the reporting of the False Negative Finding ⁶⁶.

The reporting of False Negative Finding(s), irrespective of whether it relates to routine Analytical Testing or the EQAS, or whether or not it results in the Suspension of a Laboratory's WADA

accreditation or an Analytical Testing Restriction, may trigger a WADA Laboratory on-site assessment and the requirement that the Laboratory analyses additional EQAS samples.

7.2.3 Further Procedural Evaluations ⁶⁹

If the LabEG 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 LabEG, the Laboratory will receive two (2) penalty points.

Corrective Action Reports related, for example, to nonconformities detected during Laboratory on-site assessments, or to procedural or reporting nonconformities with the ISL, 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 WADA within thirty (30) calendar days of WADA's notification to the Laboratory. Late submission of Corrective Action Reports, as determined by the LabEG, will result in the imposition of one (1) additional penalty point per five (5) working days beyond the applicable deadline, unless the Laboratory provides valid reasons for the delay, as determined by the LabEG.

Unless otherwise agreed with WADA, the corrective and preventive action(s) reported to and approved by WADA shall be implemented in the routine operations of the Laboratory immediately.

~~7.4.7.3~~ Overall Laboratory ~~evaluation~~ Evaluation

WADA shall evaluate Laboratory EQAS performance for each EQAS round, as well as Laboratory performance for routine Analytical Testing, and assign penalty points for ~~each non-compliance~~ nonconformities or ~~failure~~ failures to perform as ~~summarized~~ indicated in the ~~table~~ ISL Points Scale Table.

The accumulation of the maximum allowed number of penalty points for the EQAS and/or routine Analytical Testing, as determined in the ISL Points Scale Table below, ~~Within~~, shall prompt the WADA LabEG to make a recommendation to the Chair of the WADA Executive Committee to impose an Analytical Testing Restriction against the Laboratory or to impose a Suspension of the Laboratory's WADA accreditation, as applicable.

When the Laboratory's WADA accreditation is suspended, any ~~EQAS~~ accrued penalty points leading up to the Suspension or further accumulated through the Laboratory's participation in the blind EQAS program during the ~~round evaluation, a false Adverse Analytical Finding or the accumulation of 24 or more points will result in the provisional Suspension of accreditation until the final accreditation status~~ (Suspension period) ~~is determined by~~

⁶⁹ ISL Article 7.2.3 does not apply to the evaluation of Corrective Action Reports for False Adverse Analytical Findings or False Negative Findings, which are covered in ISL Arts. 7.2.1 and 7.2.2, respectively.

~~WADA as described in 4.4.13. WADA will consider the performance of Laboratories over the most recent~~, are reset to zero (0) upon reinstatement of its WADA accreditation⁷⁰. However, when an Analytical Testing Restriction is imposed against a Laboratory, any penalty points not related to the Analytical Testing Restriction, which were accumulated up to the imposition of the Analytical Testing Restriction or further accumulated during the Analytical Testing Restriction period (within a 12-month period ~~or the most recent and consecutive three rounds of EQAS and applicable rounds of the double blind EQAS~~⁶⁰), are carried over after the lifting of the Analytical Testing Restriction. Any ~~Laboratory that accumulates 30 or more points during this period will have its WADA accreditation provisionally Suspended until the final accreditation status (Suspension period or Revocation) is determined by WADA as described in 4.4.13~~ penalty points accrued in relation to the Analytical Testing Restriction are removed after the lifting of the Analytical Testing Restriction.

WADA is to evaluate the performance of all Laboratories based on the results in the WADA EQAS (Blind and Double Blind EQAS) as well as on issues brought to WADA's attention by stakeholders in relation to the Laboratory's routine testing services. The factors for consideration include, but are not limited to:

- ~~• False negative(s);~~
- ~~• False Adverse Analytical Finding(s);~~
- ~~• Questionable results for prohibited Threshold Substance(s);~~
- ~~• Unsatisfactory results for prohibited Threshold Substance(s);~~
- ~~• Endogenous anabolic androgenic steroid (EAAS) profiles;~~
- ~~• Questionable EAAS results;~~
- ~~• Unsatisfactory EAAS results;~~
- ~~• Improper implementation of corrective action;~~
- ~~• Responsiveness to stakeholders (WADA, NADOs, RADOs, IFs);~~
- ~~• Specific gravity;~~
- ~~• Test Report(s);~~
- ~~• Documentation package(s);~~

Point scale for assessment of Laboratory and probationary laboratory performance

⁷⁰ This provision doesn't apply to a voluntary cessation of Laboratory operations (see ISL Art. 4.6.7).

ISL Points Scale Table for Assessment of Laboratory and Probationary Laboratory Performance

Analytical Testing Conditions	Nonconformity	Type of Error Outcome	Penalty Points	Actions and Sanctions
Scoring Routine Analytical Testing (ISL Art 7.2.1.2.1)	Prohibited Substances False AAF ± Consequence for the Athlete	False Adverse Analytical Finding Technical / Methodological error or Clerical / Administrative error	2520	Immediate Cease Analytical Testing and Suspension / Analytical Testing Restriction

Split Cells

Split Cells

			False-negative	10	Corrective Action Report
	<u>Threshold Substances</u>		$ z\text{-score} \geq 3.0$	10	Corrective Action Report
			$2.0 < z\text{-score} < 3.0$	5	Internal Investigation
	Sample Parameters		$5\sigma z\text{-score} \geq 3.0$	1	Internal Investigation
	Steroid Profile concentrations	$ z\text{-score} \geq 3.0$	Occurrences**		
			4-7	2	Internal Investigation
			8-12	4	Corrective Action Report
			13-18	7	
			≥ 19	10	
	Documentation*		ISL Non-conformity	2	Corrective Action Report

Routine Analytical Testing (ISL Art 7.2.1.2.2) Or EQAS (blind or double blind) round	Technical Issue False AAF ± No Consequence	ISL Non-conformity Technical / Methodological error	220	Corrective Action Report Cease Analytical Testing
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Merged Cells

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(ISL Art 7.2.1.3)				for the <u>Athlete</u>				
▲					• Self-reporting <u>71</u>	- 5	<u>Resume Analytical Testing</u>	
					• Satisfactory and timely CAR	- 10		
<u>Evaluation</u>				Point Total for single EQAS round	• <u>≥20</u> Unsatisfactory CAR	± 5	Suspension / Analytical Testing Restriction	
▲					<u>Clerical / Administrative error</u>	15	<u>Cease Analytical Testing</u>	
					• Self-reporting <u>71</u>	- 5	<u>Resume Analytical Testing</u>	
					• Satisfactory and timely CAR	- 10		
				Double Blind EQAS point total for 12-month period***	• <u>≥20</u> Unsatisfactory CAR	± 10	Suspension / Analytical Testing Restriction	
▲	Point Total per 12 month period	≥30	Suspension <u>Routine Analytical Testing</u> Or <u>EQAS (blind or double blind) round</u> Revocation of Accreditation	False Negative Finding (ISL Art 7.2.2)				
					<u>False Negative Finding</u>	10	additional EQAS samples <u>72</u>	
					• Self-reporting <u>71</u>	- 5		
					• Satisfactory and timely CAR	- 5		

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⁷¹ Voluntary self-reporting is not applicable to blind EQAS samples.

⁷² The results of the analysis of the additional EQAS samples will be evaluated in accordance with this Points Scale Table.

		<ul style="list-style-type: none"> Unsatisfactory CAR 	+5	
--	--	--	----	--

*

Documentation includes but is not limited to Documentation Packages, Corrective Action Reports and Test Reports.

**

<u>EQAS Evaluation</u>	<u>Result</u>	<u>Penalty Points</u>
<u>Steroid Profile Markers</u> <u> z-score ≥ 3.0</u> <u>(Occurrences*)</u>	<u> z-score ≥ 3.0 and CAR</u>	
	<u>4-7</u> <u>Unsatisfactory CAR</u>	<u>2</u>
	<u>Satisfactory and timely CAR</u>	<u>1</u>
	<u>8-12</u> <u>Unsatisfactory CAR</u>	<u>4</u>
	<u>Satisfactory and timely CAR</u>	<u>2</u>
	<u>13-18</u> <u>Unsatisfactory CAR</u>	<u>6</u>
	<u>Satisfactory and timely CAR</u>	<u>3</u>
<u>GC/C/IRMS 5¹³C</u> <u>(≥ 3 Occurrences**)</u> <u>Threshold Substances</u> <u>(per occurrence)</u>	<u>2.0 < z-score < 3.0</u> <u>Internal Investigation</u>	<u>0</u>
	<u> z-score ≥ 3.0 ⁷³</u> <u>Unsatisfactory CAR</u>	<u>5</u>
	<u> z-score ≥ 3.0 ⁷³</u> <u>Satisfactory and timely CAR</u>	<u>0</u>
<u>Documentation*** or Technical Issue</u> <u>(per occurrence)</u>	<u>ISL, TD or TL Nonconformity</u>	<u>2</u>
	<u>Unsatisfactory CAR</u>	<u>2</u>
	<u>Late Submission of CAR</u> <u>(per 5 working days beyond the deadline)</u>	<u>1</u>
	<u>Late reporting of blind or double-blind EQAS results</u> <u>(per 5 working days beyond the deadline)</u>	<u>2</u>

<u>Evaluation</u>	<u>Penalty Points</u>	<u>Sanction</u>
<u>Point Total for single EQAS round (blind or double-blind****)</u>	<u>≥ 20</u>	<u>Suspension</u>
<u>Point Total for double-blind EQAS**** for 12-month period</u>		<u>Or</u>
<u>Point Total for routine Analytical Testing**** for 12-month period</u>		<u>Analytical Testing</u>
<u>Point Total (blind and double-blind EQAS and routine Analytical Testing)**** for 12-month period</u>	<u>≥ 30</u>	<u>Restriction</u>

* Based on a total of 366 determinations (estimation of six steroid variables: Androsterone-, (A), Etiocholanolone-, (Etio), Testosterone-, (T), Epitestosterone-, (E), 5α-androstane-3α,17β-diol (5αAdiol) and 5β-androstane-3α,17β-diol in six EQAS samples (5βAdiol) per EQAS round/sample.

**** Per EQAS sample subjected to GC/C/IRMS analysis.

⁷³ When an unsatisfactory (|z-score| ≥ 3.0) quantification result leads to the misreporting of the EQAS sample as a False Adverse Analytical Finding or as a False Negative Finding, then penalty points will be assigned in accordance with ISL Articles 7.2.1.3 and 7.2.2, respectively.

*** Documentation includes but is not limited to Laboratory Documentation Packages, Corrective Action Reports and Test Reports.

**** Probationary laboratories are exempt from ~~Double-Blind~~ the double-blind EQAS program and routine Analytical Testing.

AAF – Adverse Analytical Finding; CAR – Corrective Action Report

7.2.7.4 Probationary Period and Probationary Laboratory Evaluation

The probationary EQAS is a part of the initial evaluation of a probationary laboratory seeking WADA accreditation. In addition to providing blind EQAS samples, WADA may provide, upon request, samples from past EQAS rounds in order to allow the probationary laboratory an opportunity to evaluate its performance against the recorded performance of ~~WADA-accredited laboratories~~ Laboratories. Composition of the probationary EQAS samples corresponds to the criteria described in ISL Art. 6.2.2.

Successful participation in WADA probationary EQAS ~~is required before a probationary laboratory is eligible to be considered for accreditation,~~ based on point scale table ~~below~~ the ISL Points Scale Table (less than twenty (20) points accumulated within a single blind EQAS round and less than thirty (30) points for the most recent and consecutive twelve (12) month ⁶⁰ period). ~~The~~ is required before a probationary laboratory is eligible to be considered for WADA accreditation. The LabEG may decide, based on its evaluation of the overall performance of the probationary laboratory, to extend the probationary period of accreditation, even if the probationary laboratory did not reach the maximum number of penalty points based on the ISL Points Scale Table. However, once a laboratory is granted WADA accreditation, penalty points accumulated during the probationary period are annulled and are not carried forward onto the accredited phase.

The blind EQAS samples shall be distributed in multiple rounds ~~per~~each year and will consist of a minimum of ~~18~~fifteen (15) blind samples ~~per year~~. At least three (3) blind EQAS samples will contain Threshold Substances. Blank samples may also be included.

2.3.4 Methods utilized

7.4.1 Analytical Testing Procedures Utilized by Probationary Laboratories for the Analysis of EQAS samples

All procedures associated with the handling and ~~testing~~analysis of the EQAS samples by the probationary laboratory are, ~~to the greatest extent possible,~~ to be ~~carried out~~conducted using validated procedures in a manner identical to ~~that~~those expected to be applied ~~to~~during routine ~~Samples~~Analytical Testing, unless otherwise specified by WADA. ~~Methods or procedures to be utilized in routine testing should be employed.~~

7.2.7.4.2 False Adverse ~~Analytical~~Analytical Finding ~~result~~Result

Any ~~false~~False Adverse ~~Analytical~~Analytical Finding of a technical/methodological nature reported automatically suspends a probationary laboratory from further consideration for WADA accreditation. The

probationary laboratory will only be eligible for re-instatement into the accreditation process upon providing documentation to WADA that appropriate ~~remedial~~corrective and preventive ~~actions~~action(s) have been implemented. WADA may decide to send a set of EQAS samples and/or audit the probationary laboratory prior to ~~reinstatement~~its re-instatement to the probationary ~~stage~~status.

7.2.27.4.3 False ~~negative result~~Negative Finding

~~Probationary laboratories~~ Any probationary laboratory reporting a ~~false negative~~False Negative Finding in a ~~Blind~~blind EQAS round, ~~e.g. failure to identify a Prohibited Substance and/or its Metabolite(s) or Marker(s) of a Prohibited Substance or a Prohibited Method~~are shall be informed by WADA as soon as possible ~~by WADA~~. The probationary laboratory shall take and report proper corrective and preventive action(s) within ~~30~~ten (10) working days of the date of the letter ~~to~~from WADA (unless informed otherwise by WADA). ~~Probationary laboratories may otherwise be advised by WADA to take corrective action(s) or to change a corrective action which has previously been reported to WADA.~~ The corrective action ~~reported to and, if~~ approved by WADA, shall be implemented in the routine ~~operation~~operations of the probationary laboratory as soon as possible.

7.2.37.4.4 Threshold Substance ~~result~~Result

A probationary laboratory ~~is to~~shall achieve satisfactory ~~z-scores for~~ quantitative EQAS results reported based on the mean of three (3) independent determinations. ~~The relative standard deviation is to be commensurate with the validation data. The combined standard uncertainty of the procedure should not exceed that permitted in the Technical Document on Decision Limits. To report an Adverse Analytical Finding the mean result must be greater than the Decision Limit. Appropriate corrective action reported to WADA is mandatory in all cases of unsatisfactory z-scores.~~

7.2.47.4.5 Overall ~~probationary laboratory evaluation~~Probationary Laboratory Evaluation

WADA will evaluate probationary laboratory EQAS performance for each round and assign points for each ~~non-compliance~~noncompliance or failure to perform ~~as per Point in accordance with the ISL Points Scale for Assessment of Probationary Laboratory Performance table in section 3.3.5~~Table, with the exception of the double ~~blind~~ EQAS and routine analysis evaluation.

The Suspension ~~length period~~ of a probationary laboratory's participation in the EQAS ~~will~~shall be determined by WADA.

Serious and repeated issues in the probationary EQAS shall result in the ~~loss~~removal of the laboratory's status as a ~~candidate~~probationary laboratory by WADA.

~~During the probationary period other elements of the EQAS scheme, which are part of the generally applied procedures, will be considered to assess the competence of the laboratory. These elements include, but are not limited to: determination of the specific gravity of the samples, the initial determination of the endogenous anabolic androgenic steroid (EAAS) profile and the presentation of necessary documentation (test reports and the documentation package to support an Adverse Analytical Finding).~~

When ~~the~~ performance of ~~the a~~ probationary laboratory is considered to be satisfactory in the EQAS over the most recent and consecutive ~~twelve (12)~~ month ⁶⁰ period (e.g., at least ~~threefifteen (15) blind EQAS rounds~~ samples), and ~~provided that~~ all of other necessary conditions ~~having~~ have been fulfilled, the laboratory will be ~~inspected~~ audited by an ~~audit~~ assessment team appointed by WADA.

This ~~audit~~ assessment will take place while the probationary laboratory is processing and analyzing a ~~minimum of a further 20~~ fifteen (15) blind EQAS samples supplied by WADA as part of a ~~final accreditation test~~ Final Accreditation Test (FAT). The results of the ~~final accreditation test~~ FAT will be evaluated by WADA as ~~follows~~ satisfactory if:

- No ~~false~~ False Adverse ~~Analytical~~ Analytical Finding is reported;
- ~~The point total must be less~~ Less than ~~20~~ twenty (20) penalty points are assigned for the ~~20~~ EQAS samples tested;
- Any corrective actions required as a result of the ~~audit on-site assessment~~ and/or the analytical performance and/or the presentation of the requested ~~documentation packages are to~~ Laboratory Documentation Package(s) shall be submitted within ~~thirty (30) calendar days, unless otherwise specified by WADA~~ and shall be considered ~~to be~~ satisfactory by WADA.

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) working~~ calendar days prior to the end of the ~~Suspension period~~ (unless ~~informed~~ otherwise indicated by WADA). Failure to do so will ~~prohibit~~ preclude the laboratory from ~~re-entering~~ participating in the probationary EQAS. ~~Lifting of the Suspension occurs only when proper corrective action has been implemented and reported to WADA. WADA may choose, at its sole discretion, to submit additional EQAS samples to the laboratory and/or to require that the laboratory be re-audited, at the expense of the laboratory. Laboratories re-entering the probationary EQAS shall be considered as a candidate laboratory and are subject to provide the applicable fee and the required documentation to WADA.~~

Lifting of the Suspension occurs only when proper corrective and preventive actions have been implemented and reported to WADA. WADA may choose, at its sole discretion, to submit additional EQAS samples to the laboratory and/or to require that the laboratory be re-assessed, at the expense of the laboratory. Laboratories re-entering the probationary EQAS shall be considered as candidate laboratories and are subject to provide the applicable accreditation fee and the required documentation to WADA (see ISL Art. 4.2).

PART THREE: ISL ANNEXES

ISL ANNEX ~~B – LABORATORY~~A - CODE OF ETHICS FOR LABORATORIES and WADA-APPROVED LABORATORIES FOR THE ABP

3.01.0 Confidentiality

~~The Director~~Directors of Laboratories and WADA-Approved Laboratories for the ABP, their delegates and all Laboratory staff shall ~~not discuss or comment to the media on individual results prior to the completion of any adjudication without consent of the organization that supplied the Sample to the Laboratory and the organization that is asserting the Adverse Analytical Finding in adjudication~~respect and comply with Code Art. 14.3.5.

2.0 Research in Support of Doping Control

4.0 — Research

Laboratories ~~are entitled to~~shall participate in research programs, provided that the Laboratory Director is satisfied with ~~the~~their bona fide nature ⁷⁴and the ~~programs~~program(s) have received proper ethical ~~(e.g. human subjects)~~ approval, if applicable.

2.01.0 Research in Support of Doping Control

The Laboratories are expected to develop a ~~program of~~ research and development program to support 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*.

2.1 Research on Human Subjects

The Laboratories and WADA-Approved Laboratories for the ABP shall follow the Helsinki Accords and any applicable national standards as they relate to the involvement of human subjects in research. Voluntary informed consent shall also be obtained from human subjects in any drug administration studies for the purpose of development of a Reference Collection or proficiency testing materials.

⁷⁴ The Laboratory shall not engage in any research activity that undermines or is detrimental to the World Anti-doping Program.

~~Voluntary informed consent shall also be obtained from human subjects in any drug administration studies for the purpose of development of a Reference Collection or proficiency testing materials.~~

2.2 Controlled Substances

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

3.0 Analysis

~~Laboratories should exercise due diligence to ascertain that the Samples are collected according to the World Anti-Doping Code International Standard for Testing and Investigations or similar guidelines. These documents shall include collection of Samples, appropriate Sample container security considerations, and formal chain of custody conditions. Laboratories shall ensure that Samples received are tested in accordance with all the ISL rules.~~

3.1 Analytical Testing for Anti-Doping Organizations

The Laboratories and WADA-Approved Laboratories for the ABP shall accept Samples for Analytical Testing only if all of the following conditions are simultaneously met:

~~That the Samples have been collected and sealed according to the World Anti-Doping Code International Standard for Testing and Investigations or similar guidelines; met:~~

- ~~• If the~~The Sample matrix is of the proper type (e.g. blood, urine) for the requested analyses;
- ~~• The Samples have been collected, sealed and transported to the Laboratory or WADA-Approved Laboratory for the ABP in accordance with the ISTI;~~
- ~~• The~~ collection is a part of an anti-doping program; and
- ~~• If appropriate result management process will follow an Adverse Analytical Finding.~~

~~Laboratories shall not accept Samples, for the purposes of either Initial Testing or identification, from commercial or other sources when the conditions in the above paragraph are not simultaneously met.~~

~~Laboratories shall not accept Samples from individual Athletes on a private basis or from individuals or organizations acting on their behalf.~~

~~These rules apply to all sports:~~

- ~~• The Testing Authority is a Code-compliant Anti-Doping Organization.~~

~~3.4~~3.2 Clinical or Forensic Analysis

~~3.1.13.2.1~~ Occasionally the Laboratory may be requested to analyze a sample for a banned drug or endogenous substance ~~allegedly~~ coming from a hospitalized or ill ~~person~~ Person in order to assist a physician in the diagnostic process. ~~Under this circumstance~~ In such circumstances, the Laboratory Director shall ~~explain the pre-testing issue to the requester and~~ agree ~~subsequently~~ to analyze the sample only if the organization making the request provides a letter ~~accompanies~~ explaining the sample medical reason for the test and explicitly ~~certifies~~ certifying that the sample is for medical diagnostic or therapeutic purposes.

~~The letter shall also explain the medical reason for the test.~~

~~3.1.23.2.2~~ Work to aid in forensic and/or legal investigations may be undertaken but due diligence should be exercised to ensure that the work is requested by an appropriate agency or ~~body~~ organization. The Laboratory should not engage in analytical activities or expert testimony that would intentionally question the integrity of ~~the an~~ individual or the scientific validity of work performed in the anti-doping program.

3.3 Other Analytical Activities

~~3.2.1~~ Other Analytical Activities

~~3.3.1~~ The Laboratory or WADA-Approved Laboratory for the ABP shall not engage in any analysis or activity that undermines or is detrimental to the World Anti-doping Program ⁷⁵.

~~3.3.2~~ Laboratories and WADA-Approved Laboratories for the ABP shall not accept Samples from individual Athletes on a private basis or from individuals or organizations acting on their behalf.

~~3.2.43.3.3~~ If the Laboratory or WADA-Approved Laboratory for the ABP accepts Samples from any entity that is not a ~~Testing Authority recognized by the World Anti-~~ Code-compliant Anti-Doping Code Organization, it is the responsibility of the Laboratory Director ~~to ensure~~ of the Laboratory or WADA-Approved Laboratory for the ABP to receive assurance, in writing, that any Adverse Analytical Finding or Adverse Passport Finding will ~~be processed according to the Code~~ follow an appropriate results management process and that the results cannot be used in any way by an Athlete or associated Person to avoid ~~the~~ detection of doping.

~~3.2.23.3.4~~ The Laboratory ~~shall not engage in any analysis that undermines or is detrimental to the anti-doping program of WADA. The~~ Approved Laboratory should for the ABP shall not provide analytical services in a Doping Control adjudication, unless specifically requested

⁷⁵ The World Anti-Doping Program comprises the anti-doping programs of WADA and all Code Signatories, including International Federations, National Anti-Doping Organizations, Regional Anti-Doping Organizations, Major Event Organizations, the International Olympic Committee (IOC) or the International Paralympic Committee (IPC).

by the responsible Testing Authority, WADA or a Hearing Body.

~~3.2.33.3.5~~ The Laboratory shall not engage in analyzing commercial material or preparations (e.g. dietary or herbal supplements) unless specifically requested by an *Anti-Doping Organization* or WADA as part of a doping case investigation. ~~The Laboratory shall not provide~~ research program or results, ~~documentation or advice that, in any way, suggests endorsement of products or services~~ management process.

~~3.3~~ — Sharing of Information and Resources

~~3.3.1~~ — New substances

~~The WADA accredited laboratories for *Doping Control* shall inform WADA immediately when they detect a new or suspicious doping agent.~~

~~3.3.6~~ If a request pursuant to Art. 3.3.5 is made by an *Athlete*, the Laboratory may conduct the analysis if agreed by the *Anti-Doping Organization* or WADA, which may also specify conditions that must be followed prior to or during the analysis (e.g. verification of original sealed packages). The Laboratory shall not provide results, documentation or advice that, in any way, could be used as an endorsement of products or services.

Analytical activities performed under Arts. 3.2 and 3.3 above will not fall under the *WADA* accredited or approved status of the laboratory. A Laboratory or *WADA*-Approved Laboratory for the ABP shall only refer to its *WADA* accreditation or approval status, respectively, for an activity that falls under Analytical Testing for *Code-compliant Anti-Doping Organizations*.

3.4 Sharing of Knowledge

~~3.3.23.4.1~~ When information on new doping substance(s), method(s), or practice(s) is known to the Laboratory, such information shall be shared with WADA within sixty (60) calendar days ⁷⁶. When possible, the Laboratories shall share information with WADA 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, *WADA* will inform all Laboratories.

~~3.3.3~~ — Sharing of knowledge

~~3.3.43.4.2~~ When information on new substance(s), method(s), or practise(s) is known to the Laboratory Director, such information shall be shared with WADA within 60 days. This can occur by participation in scientific meetings, publication

⁷⁶ Sharing of knowledge can occur in various ways, including but not limited to directly communicating with WADA, participating in scientific meetings, publishing results of research, sharing of specific details of Analytical Methods, working with WADA to produce and/or distribute new Reference Material(s) or Reference Collection(s) or disseminating information regarding the chromatographic behaviour and mass spectra of the Analytes.

~~of results of research, sharing of specific details of methodology necessary for detection, and working with WADA to distribute information by preparation of a reference substance or biological excretion study or information regarding the chromatographic retention behaviour and mass spectra of the substance or its Metabolite(s) or Marker(s).~~ The Laboratory Director or staff shall participate in developing standards for best practice and enhancing uniformity of ~~testing~~Analytical Testing in the WADA accredited laboratory system.

4.0 Conduct Detrimental Duty to Preserve the Integrity of the World Anti-Doping Program and to Avoid any Detrimental Conduct

4.1 The ~~Laboratory~~ personnel of Laboratories and WADA-Approved Laboratories for the ABP shall not engage in conduct or activities that undermine or are detrimental to the ~~anti~~World Anti-doping program of WADA, an International Federation, a National Anti-Doping Organization, a National Olympic Committee, a Major Event Organizing Committee, or the International Olympic Committee Program. Such conduct could include, but is not limited to, ~~conviction for fraud,~~ embezzlement, perjury, etc. that would cast doubt on the integrity of the anti-doping program.

4.2 No Laboratory All employees of Laboratories and WADA-Approved Laboratories for the ABP shall strictly respect the confidentiality of Analytical Testing results, as well as of all other Laboratory or Testing Authority information, including information provided by WADA under confidentiality.

4.3 No employee or consultant of Laboratories and WADA-Approved Laboratories for the ABP shall provide counsel, advice or information to Athletes 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. ~~Outside the context of an arbitration hearing, no Laboratory~~

4.4 No employee or consultant of Laboratories and WADA-Approved Laboratories for the ABP shall provide information about a Test Method to an Athlete or Athlete Support Personnel ~~about a testing method that might assist the Athlete in avoiding, which could be used to avoid the~~ detection of ~~the Use of a Prohibited Substance or Prohibited Method. No Laboratory staff~~doping.

4.5 No staff of Laboratories and WADA-Approved Laboratories for the ABP shall assist an Athlete in avoiding collection of a representative Sample (e.g., advice on masking strategies or detection windows). ~~This paragraph does~~

[Comment: Arts. 4.3 – 4.5 do not prohibit the publication and/or presentation of scientific research results, general presentations to educate Athletes, students, or others concerning anti-doping programs and Prohibited Substances or Prohibited Methods. ~~Such provision shall remain valid for a minimum of five years following termination of the contractual link of any employee to a Laboratory.~~]

~~4.24.6~~ If ~~Laboratory~~^a staff member of a Laboratory or WADA-Approved Laboratory for the ABP is requested by either party or the tribunal to appear before an arbitration or court hearing to provide evidence in anti-doping proceedings, they are expected to provide independent, scientifically-valid expert testimony. ~~Laboratory experts should not be an advocate to either party.~~

~~4.34.7~~ The ~~Laboratory~~^a or WADA-Approved Laboratory for the ABP shall not issue ~~(publish)~~ any ~~public warning~~ statements related to the ~~Laboratory analytical processes or findings, unless otherwise provided in Code Art. 14.3.5.~~ The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be ~~left to a political decision-making body (e.g. NADO, IF or WADA); the sole responsibility of the responsible Anti-Doping Organization(s) or WADA.~~

5.0 -Breach and Enforceability

A failure to respect any of the provisions of this Code of Ethics may result in the Laboratory or WADA-Approved Laboratory for the ABP being subject to Disciplinary Proceedings instituted by WADA to either suspend or revoke its WADA accreditation or its WADA approval, as applicable, in accordance with ISL Art. 4.6.4.5.

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

ISL ANNEX B – PROCEDURAL RULES FOR THE DISCIPLINARY COMMITTEE OF THE INTERNATIONAL STANDARD FOR LABORATORIES

Preamble

These Procedural Rules for the Disciplinary Committee (DC) of the ISL (the “Procedural Rules”) outline the process to be followed when a Laboratory appeals a recommendation of the LabEG in accordance with ISL Art. 4.6.4.1.2, when a Laboratory is subject to Revocation proceedings in accordance with ISL Art. 4.6.4.3 or, when and where applicable, Disciplinary Proceedings are instituted against a WADA-Approved Laboratory for the ABP in accordance with ISL Art. 4.8.4.1. In such circumstances, any reference made to a Laboratory in these Procedural Rules shall be understood as a reference to a WADA-Approved Laboratory for the ABP, unless such reference is not applicable due to the circumstances, specific nature or rules indicated in this ISL in relation to WADA-Approved Laboratories for the ABP.

These Procedural Rules shall be considered as an integral part of the ISL.

PART I - Composition of the Committee

Art. 1

For each individual case, a DC shall be constituted. It shall be composed of three (3) members including a Chairperson.

WADA's Director General shall appoint the three (3)-member DC for each case and decide which one will serve as Chairperson.

The appointed members shall have a legal and/or scientific background with at least one member being an anti-doping expert and one with legal training and education (including the Chairman). The Chairman shall in any event have experience in the conduct of disciplinary or legal proceedings.

All members of an appointed DC shall be free of any conflict of interest with WADA, the Laboratory concerned, or any other Laboratory, entity, organization or individual that could potentially benefit from the concerned Laboratory's Suspension, Revocation or Analytical Testing Restriction, and must otherwise be impartial in relation to WADA and the Laboratory concerned. The anti-doping laboratory expert(s) may be member(s) of the WADA Laboratory Expert Group (LabEG), unless the case has been the subject of previous discussion or recommendation by the LabEG.

All DC members shall sign a declaration in which they confirm their impartiality and mention any circumstance, which may be relevant in this respect.

Art. 2

If the impartiality of any member of the DC is challenged (for example, by the Laboratory), the matter shall be decided by the Chairperson if he is not the concerned DC member or by the two other DC

members if the challenge concerns the Chairperson. In the event the two DC members cannot agree, WADA's Director General shall make the decision.

The decision is not subject to an independent challenge.

PART II - General Provisions

Art. 3

3.1 Once the DC is constituted, WADA will provide it with the complete case file, including all of the evidence it wishes to submit in support of the disciplinary action being taken against the Laboratory. WADA may send the case file and any information to the DC electronically or by registered mail.

3.2 Simultaneously, WADA shall provide the Laboratory with the complete case file and with all of the available supporting evidence. WADA may send the case file and any information to the Laboratory electronically or by registered mail.

3.3 Within five (5) business days of receiving the full case file, the Laboratory may respond in writing and provide all of its evidence to the DC and shall also simultaneously provide copies of all its submissions and evidence to WADA's Legal Department. Any requests to extend this deadline shall be addressed by the Laboratory to the Chairperson of the DC, who shall have the discretion to grant or reject the requested extension.

3.4 Upon receipt of the Laboratory's submissions and evidence, WADA shall have five (5) business days to make rebuttal submissions to the Disciplinary Committee. Any requests to extend this deadline shall be addressed by WADA to the Chairperson of the DC, who shall have the discretion to grant or reject the requested extension.

3.5 If the Laboratory fails or chooses not to respond or provide evidence within the required time frame, the disciplinary proceedings will continue on the basis of the evidence at the disposal of the DC.

Art. 4

Unless both parties agree otherwise or the Chairperson orders otherwise on the basis of exceptional circumstances, the parties shall not be permitted to include additional material after the submission of the final evidence packages in accordance with the procedure described in Art. 3 above.

Art. 5

The working language of the DC shall be English. The DC may accept documents in other languages at its discretion.

PART III - Scope of the Committee's Review

Art. 6

6.1 The DC shall have the authorization to review the evidence of the case and to make a recommendation regarding the status of the Laboratory's WADA accreditation.

6.2 To the extent not otherwise provided in these "Procedural Rules", the Chairperson may issue directions regarding procedural matters to the parties.

6.3 The DC shall have the right to appoint one or more independent expert(s) should it consider that particular expertise is required in order for it to make its recommendation to maintain, suspend or revoke a Laboratory's WADA accreditation or to impose an Analytical Testing Restriction.

6.4 After consulting the parties, the DC may, if it deems itself to be sufficiently well informed, decide not to hold a hearing and it may determine its recommendation based on the parties' written submissions and the available documents.

6.5 The DC shall make its recommendation in accordance with the applicable regulations, including the Code, the ISL and any relevant Technical Documents or Technical Letters, or any other rules or law agreed to by WADA and the Laboratory, and by default, Swiss law.

6.6 The DC's decisions, including the content of its recommendation, shall be by majority.

PART IV - Recommendation

Art. 7

7.1 The recommendation of the DC shall be issued in writing, with reasons ⁷⁷, within fourteen (14) calendar days of the conclusion of the hearing. If no hearing is held, the DC shall issue its recommendation within fourteen (14) calendar days of the communication to the parties that no hearing will be held.

7.2 Where the DC considers that a Laboratory's accreditation should be suspended or subject to an Analytical Testing Restriction, it shall recommend a period of Suspension or Analytical Testing Restriction that is proportionate to the seriousness of the noncompliance(s) with the ISL and/or Technical Document(s) and/or Technical Letters and the need to ensure accurate and reliable Analytical Testing of Samples.

7.3 The DC may recommend to the Chair of the WADA Executive Committee that a Laboratory's WADA accreditation be suspended or subjected to an Analytical Testing Restriction for a period of up to six (6) months (with one possible extension of up to six (6) months). During this time, any ISL and/or Technical Document and/or Technical Letter noncompliance(s) identified within the context of the Disciplinary Proceedings instituted against the Laboratory and resulting in the Suspension of its WADA accreditation or the imposition of an Analytical Testing Restriction, or during a subsequent on-site assessment conducted by WADA during the Laboratory's Suspension or during the period of the Analytical Testing Restriction, shall be corrected, documented, reported to WADA and determined to be satisfactory by

⁷⁷ The decision may be summarily reasoned.

WADA. The DC shall also indicate any conditions that the Laboratory shall satisfy prior to the reinstatement of the Laboratory's WADA accreditation.

7.4 In cases where it considers that it is appropriate to do so, the DC may also recommend that the Laboratory receive a warning with no period of Suspension or no imposition of an Analytical Testing Restriction.

7.5 The recommendation of the DC shall be provided to the Chair of the WADA Executive Committee without delay.

7.6 If the DC recommends the Suspension of the Laboratory's WADA accreditation or the imposition of an Analytical Testing Restriction, the Chair of the WADA Executive Committee shall render a final decision regarding the Suspension of the Laboratory's WADA accreditation or the imposition of an Analytical Testing Restriction within ten (10) calendar days of receiving the DC's recommendation.

7.7 If the DC recommends the Revocation of the Laboratory's WADA accreditation, the WADA Executive Committee shall render a decision regarding the Revocation of the Laboratory's WADA accreditation within ten (10) calendar days of receiving the DC's recommendation.

7.8 If the DC recommends that the Laboratory shall maintain its WADA accreditation, the Laboratory shall be informed accordingly by WADA within seven (7) calendar days of receiving the DC's recommendation.