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WORLD ANTI-DOPING CODE

INTERNATIONAL STANDARD

LABORATORIES

2021

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International Standard for Laboratories

The World Anti-Doping Code *International Standard* for Laboratories is a mandatory *International Standard* developed as part of the World Anti-Doping Program. It was developed in consultation with *Signatories*, public authorities, and other relevant stakeholders.

The *International Standard* for Laboratories first came into effect in November 2002. It was subsequently amended multiple times, specifically in 2003, 2004, 2008, 2009, 2012, 2015, 2016, and 2019. A revised version was approved by the *WADA* Executive Committee on 15 September 2020 and is effective as of 1 January 2021.

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Table of Contents

PART ONE: INTRODUCTION, *CODE* PROVISIONS, *INTERNATIONAL STANDARD* PROVISIONS AND DEFINITIONS

1.0 Introduction and Scope

1.1 *WADA* Laboratory Standards

1.1.1 *International Standard* for Laboratories (ISL)

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."

The main purpose of the ISL is to ensure that Laboratories and *ABP* Laboratories 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 *ABP* Laboratories.

The ISL sets out the requirements to be followed by Laboratories and *ABP* Laboratories 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 *ABP* Laboratories and a description of the accreditation and approval processes. The ISL also sets out requirements and guidance for *Anti-Doping Organizations* in relation to *Sample* custody and storage, Analytical *Testing* and some aspects of *Results Management*.

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

1.1.2 *Technical Documents*

- *Technical Documents* are issued to provide direction to the Laboratories, *ABP* Laboratories 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* becomes an integral part of the ISL and supersedes any previous publication on a similar topic [1], including Technical Letter(s) and/or the ISL.
- Implementation of the requirements detailed in a *Technical Document* may occur prior to the effective date for implementation specified in the *Technical Document* and shall occur no later than the effective date.

A failure by a Laboratory or *ABP* Laboratory to implement a *Technical Document* or Technical Letter by the effective date may result in the imposition of an Analytical *Testing* Restriction against the Laboratory for that 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*;

[Comment: Laboratories and ABP Laboratories 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 ABP Laboratory's Standard Operating Procedure(s) [SOP(s)]. If a Laboratory or ABP Laboratory is not able to implement a new Technical Document by its effective date, it shall inform its clients and WADA as soon as possible. The Laboratory or ABP Laboratory shall send a written request to WADA for an extension beyond the applicable effective date, providing the reason(s) for the delayed implementation of the Technical Document, any measures taken to ensure that Samples received in the Laboratory or ABP Laboratory will be subject to Analytical Testing in compliance with the new Technical Document (for example, by subcontracting the analysis to another Laboratory or ABP Laboratory, as applicable), as well as plans for the implementation of the new Technical Document.]

- The implementation of the *Technical Documents* requirements into the Laboratory's and, if relevant to the analysis of *ABP* blood *Sample*s, the *ABP* Laboratory'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 a *Decision Limit* for a Threshold Substance or a *Minimum Reporting Level* for a Non-Threshold Substance, as applicable, the revised limits specified in the new

[1] *WADA* will provide guidance to Laboratories, *ABP* Laboratories and other *WADA* stakeholders on the standard(s) that 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.

Technical Document shall not be applied to the reporting of analytical results for *Samples* collected before the effective date of the *Technical Document*.

[Comment: For example, if the application of a newly approved Technical Document results in an Adverse Analytical Finding for a Sample with a collection date prior to the effective date of that new Technical Document, which would not have resulted in an Adverse Analytical Finding with the application of the currently effective version of the Technical Document in effect at the time of Sample collection (for example if 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.]

- The most recently approved *Technical Document* shall be applied to the Analytical *Testing* of *Samples* prior to the effective date if it would lead to a result that benefits the *Athlete* (*e.g.* increase of the *Decision Limit* for a Threshold Substance or of the *Minimum Reporting Level* 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.

1.1.3 Technical Letters

- Technical Letters are issued in letter format on an *ad-hoc* basis in order to provide direction to the Laboratories, *ABP* Laboratories 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 *WADA*;

  [Comment: 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.]
- Once approved, a Technical Letter becomes an integral part of the ISL and supersedes any previous publication on a similar topic[1], including *Technical Document(s)* and/or 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*, the *ABP* Laboratory'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.*

1.1.4 Laboratory Guidelines

- Laboratory Guidelines are issued in order to provide direction to the Laboratories, *ABP* Laboratories 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 Laboratory Expert Group (LabEG) and are published on *WADA*'s website;
- Implementation of Laboratory Guidelines is not mandatory. However, Laboratories and *ABP* Laboratories are encouraged to follow, to the fullest extent possible, the recommendations of best practice included in relevant Laboratory Guidelines.

1.1.5 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 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.

1.2 *Sample* Analysis

Sample analysis is part of the Analytical *Testing* process and involves the detection, identification, and in some cases demonstration of the presence above a Threshold of *Prohibited Substance(s)* and/or their *Metabolite(s)*, or *Marker(s)* of *Use* of *Prohibited Substances* or *Prohibited Methods* in human biological fluids or tissues.

Laboratories may accept samples for other forms of analysis, subject to the provisions of the ISL Code of Ethics (see Annex A), which are not under the scope of *WADA* accreditation (*e.g.* animal sports testing, forensic testing, clinical testing, drugs of abuse testing). Any such testing shall not be covered by 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, test reports or other documentation or correspondence from Laboratories shall not declare or represent that any such testing is covered under their *WADA* accreditation status.

ABP Laboratories may also accept samples for 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 or other documentation or correspondence from *ABP*

Laboratories shall not state or represent that any such testing is covered under their *WADA* approval status.

1.3 *WADA* Laboratory Accreditation Framework and Laboratory Approval for the *ABP*

The *WADA* Laboratory accreditation and Laboratory approval for the *ABP* framework consists of two main elements: Part Two of the ISL (Laboratory accreditation and Laboratory approval for the *ABP* 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, as well as the requirements necessary to obtain and maintain *WADA* approval for the *ABP* (Section 4.0). It also includes the application of ISO/IEC 17025 [2] to the field of *Doping Control* (Section 5.0) and a description of the *WADA* External Quality Assessment Scheme (EQAS) (Section 6.0) as well as the procedures to evaluate Laboratory EQAS and routine Analytical *Testing* performance by *WADA* (Section 7.0). The purpose of Part Two of the ISL is to enable the consistent application of ISO/IEC 17025 and ISL-specific requirements to Analytical *Testing* for *Doping Control* by Laboratories and *ABP* Laboratories, as well as to facilitate the assessment of Laboratory and *ABP* Laboratory compliance by Accreditation Bodies and *WADA.*
- Part Three of the ISL includes all Annexes. Annex A (Code of Ethics), Annex B (Accreditation and Analytical *Testing* Requirements for Major *Events*) and Annex C (Procedural Rules) describe the ethical and legal standards required for continued *WADA* accreditation of the Laboratory or continued approval of the laboratory for the *ABP*, as well as the specific requirements to conduct Analytical *Testing* during Major *Events*.

In order to harmonize the accreditation of Laboratories to the requirements of ISO/IEC 17025 and the approval of *ABP* Laboratories to the requirements of ISO/IEC 17025 (or ISO 15189), as well as the *WADA*-specific requirements for accreditation or approval, Accreditation Bodies are required to use the ISL, including the applicable Annexes, *Technical Documents*, Technical Letters and Laboratory Guidelines as reference documents in their assessment process.

[Comment: While Laboratories are required to be accredited to the requirements of ISO/IEC 17025 (applicable to testing and calibration laboratories), ABP Laboratories may be accredited to either the ISO/IEC 17025 or ISO 15189 (applicable to medical laboratories) standards].

Maintenance of a laboratory's *WADA* accreditation or approval for the *ABP* is based on satisfactory performance in the applicable EQAS and in routine Analytical *Testing*. The EQAS performance of Laboratories and *ABP* Laboratories is continually monitored by *WADA* and reviewed as part of their Accreditation Body assessment process, as applicable. Therefore, the Laboratory or *ABP* Laboratory shall not be subject to challenge or to demands to produce EQAS data or related EQAS documentation by third parties.

[2] Effective version of ISO/IEC 17025.

Terms used in this *International Standard* that are defined terms from the *Code* are italicized. Terms that are defined in this or another *International Standard* are underlined.

2.0 *Code* Provisions

The following articles in the 2021 *Code* are directly relevant to the *International Standard* for Laboratories, they can be obtained by referring to the *Code* itself:

- *Code* Article 2 Anti-doping Rule Violations
- *Code* Article 3 Proof of Doping
- *Code* Article 4 The *Prohibited List*
- *Code* Article 6 Analysis of *Samples*
- *Code* Article 10 Sanctions of Individuals
- *Code* Article 13 *Results Management:* Appeals
- *Code* Article 14 Confidentiality and Reporting

3.0 Definitions and Interpretations

3.1 Defined terms from the 2021 *Code* that are used in the *International Standard* for Laboratories

***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 establishes in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* or evidence of the *Use* of a *Prohibited Method*.

***Anti-Doping Organization*:** *WADA* or 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*, 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 elected to exercise its authority to test and who competes below the international or national level, then the *Consequences* set forth in the *Code* 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: Individuals who participate in sport may fall in one of five categories: 1) International-Level Athlete, 2) National-Level Athlete, 3) individuals who are not International or National-Level Athletes but over whom the International Federation or National Anti-Doping Organization has chosen to exercise authority, 4) Recreational Athlete, and 5) individuals over whom no International Federation or National Anti-Doping Organization has, or has chosen to, exercise authority. 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.]

***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*.

***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 Violations ("Consequences")*:** 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 *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* 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.

***Decision Limit*:** The value of the result for a Threshold Substance in a *Sample*, above which an *Adverse Analytical Finding* shall be reported, as defined in the *International Standard* for Laboratories.

***Delegated Third Parties*:** Any *Person* to which an *Anti-Doping Organization* delegates any aspect of *Doping Control* or anti-doping Education programs including, but not limited to, third parties or other *Anti-Doping Organizations* that conduct *Sample* collection or other *Doping Control* services or anti-doping Educational programs for the *Anti-Doping Organization*, or individuals serving as independent contractors who perform *Doping Control* services for the *Anti-Doping Organization* (e.g., non-employee *Doping Control* officers or chaperones) This definition does not include *CAS*.

***Doping Control*:** All steps and processes from test distribution planning through to ultimate disposition of any appeal and the enforcement of *Consequences*, including all steps and processes in between, including but not limited to, *Testing*, investigations, whereabouts, *TUEs*, *Sample* collection and handling, laboratory analysis, *Results Management*, and investigations or proceedings relating to violations of Article 10.14 (Status During *Ineligibility* or *Provisional Suspension*).

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

***In-Competition*:** The period commencing at 11: 59 pm on the day 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*. Provided, however, *WADA* may approve, for a particular sport, an alternative definition if an International Federation provides a compelling justification that a different definition is necessary for its sport; upon such approval by *WADA*, the alternative definition shall be followed by all *Major Event Organizations* for that particular sport.

[Comment: Having a universally accepted definition for In-Competition provides greater harmonization among Athletes across all sport, eliminates or reduces confusion among Athletes about the relevant timeframe for In-Competition Testing, avoids inadvertent Adverse Analytical Findings in between Competitions during an Event and assists in preventing any potential performance enhancement benefits from substances prohibited Out-of-Competition being carried over to the Competition.]

***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*.

***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.

***Minimum Reporting Level*:** The estimated concentration of a *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* in a *Sample* below which *WADA*-accredited laboratories should not report that *Sample* as an *Adverse Analytical Finding*.

***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*.

***Results Management*:** The process encompassing the timeframe between notification as per Article 5 of the *International Standard* for *Results Management*, or in certain cases (*e.g.*, *Atypical Finding*, *Athlete Biological Passport*, Whereabouts Failure), such pre-notification steps expressly provided for in Article 5 of the *International Standard* for *Results Management*, through the charge until the final resolution of the matter, including the end of the hearing process at first instance or on appeal (if an appeal was lodged).

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

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

***Tampering*:** Intentional conduct which subverts the *Doping Control* process, but which would not otherwise be included in the definition of *Prohibited Methods*. *Tampering* shall include, without limitation, offering or accepting a bribe to perform or fail to perform an act, preventing the collection of a *Sample*, affecting or making impossible the analysis of a *Sample*, falsifying documents submitted to an *Anti-Doping Organization* or *TUE* committee or hearing panel, procuring false testimony from witnesses, committing any other fraudulent act upon the *Anti-Doping Organization* or hearing body to affect *Results Management* or the imposition of *Consequences*, and any other similar intentional interference or *Attempted* interference with any aspect of *Doping Control*.

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

***Technical Document*:** A document adopted and published by *WADA* from time to time containing mandatory technical requirements on specific anti-doping topics as set forth in an *International Standard*.

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

***Therapeutic Use Exemption (TUE)*:** A *Therapeutic Use Exemption* allows an *Athlete* with a medical condition to *Use* a *Prohibited Substance* or *Prohibited Method*, but only if the conditions set out in Article 4.4 and the *International Standard* for *Therapeutic Use Exemptions* are met.

***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.

3.2 Defined Terms from the *International Standard* for Laboratories

***ABP* Laboratory:** A laboratory not otherwise accredited by *WADA,* which is approved by *WADA* to 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*.

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

Analyte: Also known as or referred to as a substance, compound or measurand, which is analyzed and/or determined in a biological matrix using an Analytical *Testing* Procedure performed under controlled analytical and laboratory conditions. For anti-doping purposes, an Analyte may be a *Prohibited Substance*, a *Metabolite* of a *Prohibited Substance*, or a *Marker* of the *Use* of a *Prohibited Substance* or *Prohibited Method*.

Analytical Method: Analytical *Testing* Procedure, Test Method.

Analytical *Testing*: The parts of the *Doping Control* process performed at the Laboratory, which include *Sample* handling, analysis and reporting of results.

Analytical *Testing* Procedure: A Fit-for-Purpose procedure, as demonstrated through method validation, and used to detect, identify and/or quantify Analytes in a *Sample* for *Doping Control* purposes in accordance with the 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.

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

***Athlete* Passport Management Unit (APMU):** A unit composed of a *Person* or *Persons* that is responsible for the timely management of *Athlete Biological Passports* in *ADAMS* on behalf of the Passport Custodian.

Bias (*b*): Deviation of a measured result from the expected or reference value when using the complete measurement procedure.

Certificate of Analysis: The material produced by a Laboratory or *ABP* Laboratory upon request by an APMU, Expert Panel, or *WADA* as set forth in the *Technical Document* on Laboratory Documentation Packages (TD LDOC), to support an analytical result for a *Sample* that is judged to confirm the baseline level of a urine or blood *Marker* of the *Athlete Biological Passport*.

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

Confirmation Procedure (CP): An Analytical *Testing* Procedure that has the purpose of confirming the presence and/or, when applicable, confirming the concentration/ratio/score and/or establishing the origin (exogenous or endogenous) of one or more specific *Prohibited Substances*, *Metabolite(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* in a *Sample*.

Corrective Action Report (CAR): A report describing the Root Cause Analysis investigation of a detected nonconformity and the corrective actions implemented to rectify it. If appropriate, it shall also describe the improvements adopted to minimize the risk of recurrence of the nonconformity.

[Comment: The term "Corrective Action" is widespread in the ISO standards for laboratories and it is used to describe the actions that ought to be taken by a laboratory in cases of nonconformities that occur during the performance of its work. This term is recognized as one of the minimum items that the laboratory Management System shall address. Thus, corrective action reports (CARs) are used by accreditation bodies all over the world to understand and assess the treatment of nonconformities by laboratories, including an analysis of the extent and cause (i.e. root cause analysis) of the nonconformities.]

External Quality Assessment Scheme (EQAS): 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 *Prohibited Substances* and/or their *Metabolite(s),* or *Marker(s)* of *Use* of *Prohibited Substances* or *Prohibited Methods*. The EQAS includes also the provision of blood samples to *ABP* Laboratories for the analysis of the blood *Markers* of the *Athlete Biological Passport*. 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).

Fit(ness)-for-Purpose: 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).

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

[Comment: The concept of flexible scope of accreditation may also be applied, as determined by the Accreditation Body, to the analysis of ABP blood Markers when included in the scope of ISO 15189 accreditation of ABP Laboratories.]

Further Analysis: *Further Analysis, as this term is used in the ISL, occurs when a Laboratory conducts additional analysis on an "A" Sample or a "B" Sample after an analytical result for that "A" Sample or that "B" Sample has been reported by the Laboratory.*

[Comment: There is no limitation on a Laboratory's authority to conduct repeat or confirmation analysis, or to analyze a Sample with additional Analytical Methods, or to perform any other type of additional analysis on an "A" Sample or "B" Sample prior to reporting an analytical result on that Sample. That is not considered Further Analysis.

If a Laboratory is to conduct additional analysis on an "A" Sample or "B" Sample after an analytical result for that Sample has been reported (for example: additional Sample analysis to detect EPO, or GC/C/IRMS analysis, or analysis in connection with the Athlete Biological Passport or additional analysis on a stored Sample) it may do so after receiving approval from the Testing Authority or Results Management Authority (if different) or WADA. However, after an Athlete has been charged with a Code Article 2.1 anti-doping rule violation based on the presence of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method in a Sample, then Further Analysis on that Sample may only be performed with the consent of the Athlete or approval from a hearing body (see Code Article 6.5).

Further Analysis may be performed 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 Testing Authority or Results Management Authority (if different) 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 Testing Authority or Results Management Authority (if different) 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 Anti-Doping Organization's expense.]

Independent Witness: A *Person*, invited by the *Testing* Authority, the Laboratory or *WADA* to witness the opening and initial aliquoting of an *Athlete's* "B" *Sample*. An Independent Witness shall not be an employee or have a personal financial relationship with the *Athlete* or his/her representative(s), the Laboratory, the *Sample* Collection Authority, the *Testing* Authority / *Delegated Third Parties* / *Results Management* Authority or *WADA*, as applicable. However, 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.

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*.

[Comment: 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: A *WADA*-accredited laboratory 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 Expert Group (LabEG): Group of laboratory experts responsible for providing advice, recommendations and guidance to *WADA* with respect to the overall management of anti-doping Laboratory accreditation and *ABP* approval, Laboratory and *ABP* Laboratory disciplinary action, re-accreditation and approval processes as well as Laboratory and *ABP* Laboratory monitoring activities.

Laboratory Guidelines (LGs): 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.

[Comment: 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 LabEG].

Laboratory Documentation Package (LDP): The material produced by a Laboratory upon request by the *Testing* Authority, *Results Management* Authority or *WADA*, as set forth in the *Technical Document* on Laboratory Documentation Packages (TD LDOC), to support an analytical result such as an *Adverse Analytical Finding* or an *Atypical Finding*.

Limit of Detection (LOD): Analytical parameter of assay technical performance. Lowest concentration of an Analyte in a *Sample* that can be routinely detected, but not necessarily identified or quantified, under the stated Test Method conditions.

Limit of Identification (LOI): Analytical parameter of technical performance for chromatographic-mass spectrometric Confirmation Procedures. The LOI is estimated during method validation to evaluate the rate of false negative results at a certain concentration level. The LOI of a Test Method, at 5% false negative rate, for an Analyte (for which a Reference Material is available) shall be less than the MRPL.

[Comment: Since the LOI is an estimation of the false negative rate, Laboratories may report findings below the estimated LOI as Adverse Analytical Findings or Atypical Findings, as applicable, when the Analyte is identified in the Sample according to the criteria established in the Technical Document on chromatographic-mass spectrometric identification criteria (TD IDCR).]

Limit of Quantification (LOQ): Analytical parameter of assay technical performance. Lowest concentration of an Analyte in a *Sample* that can be quantitatively determined with acceptable precision and accuracy (*i.e.* acceptable Measurement Uncertainty) under the stated Test Method conditions.

Major *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).

Measurement Uncertainty (MU): Parameter associated with a measurement result that characterizes the dispersion of quantity values attributed to the measure and provides confidence in the validity of the measured result [see *Technical Document* on *Decision Limits* (TD DL)].

Minimum Required Performance Level (MRPL): Minimum analytical criterion of Laboratory technical performance established by *WADA*. Minimum concentration at which a Laboratory is expected to consistently detect and confirm a *Prohibited Substance* or *Metabolite* of a

Prohibited Substance or *Marker* of a *Prohibited Substance* or *Prohibited Method* in the routine daily operation of the Laboratory. Individual Laboratories may and are expected to achieve better performance [see *Technical Document* on Minimum Required Performance Levels (TD MRPL)].

Negative Finding: 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 *Prohibited Substance(s)* or its *Metabolite(s)* or *Marker(s)* or evidence of the *Use* of a *Prohibited Method(s)*, included in the requested Analytical *Testing* menu, were found in a *Sample* based on the applied Initial *Testing* Procedure(s) or Confirmation Procedure(s).

Non-Threshold Substance: A substance listed on the *Prohibited List* for which the identification, in compliance with the *Technical Document* on chromatographic-mass spectrometric identification criteria (TD IDCR) or other applicable *Technical Document(s)*, constitutes an *Adverse Analytical Finding*.

Presumptive *Adverse Analytical Finding* (PAAF): The status of a *Sample* test result from the Initial *Testing* Procedure which represents a suspicious finding, but for which a Confirmation Procedure to render a conclusive test result has not yet been performed.

Provisional Suspension: Temporary Suspension of a Laboratory's *WADA* accreditation or a laboratory's *ABP* approval pending a final decision by *WADA* regarding its accreditation status.

Reference Collection (RC): A collection of samples or isolates of known origin that may be used in the determination of the identity of an unknown substance. For example, a well-characterized sample obtained from a controlled administration or from *in vitro* studies in which the presence of the substance of interest has been established.

Reference Material (RM): Reference Substance or Reference Standard, which is sufficiently characterized, homogeneous and stable with respect to one or more specified properties and that has been established to be fit for its intended use in an Analytical *Testing* Procedure.

Repeatability (s_r): Variability of results obtained within a laboratory using the same method, over a short time, using a single operator, item of equipment, etc. It is also referred to as intra-batch / intra-run precision.

Reproducibility (s_R): 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.

Revocation: The permanent withdrawal of a Laboratory's *WADA* accreditation or a laboratory's *ABP* approval.

Root Cause Analysis (RCA): An investigation to identify one or more fundamental cause(s) of a nonconformity based on the collection of objective evidence from an assessment of the likely factors that led to the nonconformity. The removal of a root cause factor prevents the recurrence of the nonconformity; in contrast, removing a causal factor can improve the outcome, but it does not prevent the recurrence of the problem with certainty.

Selectivity: The ability of the Analytical *Testing* Procedure to detect or identify, as applicable, the substance of interest in the *Sample*.

Suspension: The temporary withdrawal of a Laboratory's *WADA* accreditation or a laboratory's *ABP* approval.

Technical Letter (TL): Mandatory technical requirements provided by *WADA* 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 *ABP* Laboratory procedures.

[Comment: Technical Letters are approved by the WADA Executive Committee and posted on WADA's website. Technical Letters become effective immediately, unless otherwise specified by WADA].

Technical Note (TN): Technical guidance provided by *WADA* to Laboratories on the performance of specific Laboratory methods or procedures.

[Comment: Technical Notes are not considered part of Technical Documents and therefore are not of mandatory application. Technical Notes are approved by the LabEG 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).

3.3 Defined Terms from the *International Standard* for *Testing* and Investigations

***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) a *Delegated Third Party* to whom the authority to conduct *Testing* has been granted or sub-contracted. 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 their *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 Article 4 of the *International Standard* for *Testing* and Investigations.

***Testing* Authority:** The *Anti-Doping Organization* that authorizes *Testing* on *Athletes* it has authority over. It may authorize a *Delegated Third Party* to conduct *Testing* pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization.* Such

authorization shall be documented. The *Anti-Doping Organization* authorizing *Testing* remains the *Testing* Authority and ultimately responsible under the *Code* to ensure the *Delegated Third Party* conducting the *Testing* does so in compliance with the requirements of the *International Standard* for *Testing* and Investigations.

3.4 Defined Terms from the *International Standard* for *Results Management*

Passport: A collation of all relevant data unique to an individual *Athlete* that may include longitudinal profiles of *Markers*, heterogeneous factors unique to that particular *Athlete* and other relevant information that may help in the evaluation of *Markers*.

Passport Custodian: The *Anti-Doping Organization* responsible for *Result Management* of the *Athlete*'s Passport and for sharing any relevant information associated to that *Athlete*'s Passport with other *Anti-Doping Organization*(s).

***Results Management* Authority:** The *Anti-Doping Organization* responsible for conducting *Results Management* in a given case.

3.5 Interpretation

3.5.1 The official text of the *International Standard* for Laboratories shall be published in English and French. In the event of any conflict between the English and French versions, the English version shall prevail.

3.5.2 Like the *Code*, the *International Standard* for Laboratories has been drafted giving consideration to the principles of proportionality, human rights, and other applicable legal principles. It shall be interpreted and applied in that light.

3.5.3 The comments annotating various provisions of the *International Standard* for Laboratories shall be used to guide its interpretation.

3.5.4 Unless otherwise specified, references to Sections and Articles are references to Sections and Articles of the *International Standard* for Laboratories.

3.5.5 Where the term "days" is used in the *International Standard* for Laboratories, it shall mean calendar days unless otherwise specified.

3.5.6 The Annexes to the *International Standard* for Laboratories have the same mandatory status as the rest of the *International Standard*.

PART TWO: LABORATORY ACCREDITATION AND LABORATORY APPROVAL FOR THE *ABP* REQUIREMENTS AND OPERATING STANDARDS

4.0 Process and Requirements for *WADA* Laboratory Accreditation and Laboratory Approval for the *ABP*

This section describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining *WADA* accreditation or *WADA* approval for the *ABP*.

4.1 Applicant Laboratory for *WADA* 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, at 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

The applicant laboratory shall officially contact *WADA* in writing to express its interest in becoming a *WADA*-accredited laboratory.

4.1.2 Submit Initial Application Form

The applicant laboratory shall submit a completed Application Form, provided by *WADA*, duly signed by the laboratory Director and, if relevant, by the Director of the host organization (*e.g.* university, hospital, public institution).

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 Standard*s 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.

4.1.3 Provision of Letters of 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 organizations acceptable to *WADA* (*e.g.* universities, hospitals, private organizations and/or public institutions) that

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

- Official letter(s) of support from *Signatories,* 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 *Samples* per year by the end of the second calendar year after obtaining *WADA* accreditation;

  [Comment: 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.]

- A declaration by the supporting *Signatory(-ies)* that their relationship with the applicant laboratory is compliant with Article 4.4.2.4.

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 for *WADA* Accreditation

The application materials described in Articles 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 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:

- 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 secure and restricted access

to the laboratory facility and a controlled internal laboratory environment (*e.g.* dedicated and restricted *Sample* storage areas, CCTV monitoring);

- IT Security: implementation of firewalls and other cyber security measures consistent with best practice and any applicable governmental regulations (see Article 5.2.3.5);
- Information Technology (IT) infrastructure: implementation of a data and information management system (*e.g.* LIMS), central server/intranet which allows secure data handling (see Article 5.2.3.5).

- List of actual and proposed instrumental resources and equipment, including year of purchase and conditions for technical support (*e.g*. contract/access to instrument manufacturer maintenance services);
- 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 Reference Collections, or plans to acquire Reference Materials or obtain Reference Collections;
- Plans to ensure compliance with laboratory independence and impartiality requirements before receiving *WADA* accreditation (see Article 4.4.2.4);
- List of laboratory sponsors;
- Contract or Memorandum of Understanding with a Laboratory, which will provide mentoring and training for at least the period spanning the probationary phase of accreditation;

[Comment: Candidate laboratories are encouraged to establish agreement(s) with a Laboratory(-ies) for mentoring and training, at least, up to the end of the probationary phase of accreditation in order to ensure successful preparation towards obtaining the WADA accreditation.

An authorization for the candidate laboratory to receive sensitive anti-doping information (e.g. methodological or technological information, Technical Notes) and/or to obtain access to specific, WADA-developed anti-doping tests or materials (e.g. kits, Reference Materials) may be approved by WADA on a case-by-case basis according to the documented roadmap, business plan and the progress made during the accreditation process and subject to the candidate laboratory entering into a confidentiality agreement with WADA and/or the Laboratory(-ies) that will provide the information and/or access to the aforementioned tests and materials.]

- 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;

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

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

4.2.2 Payment of Initial Accreditation Fee

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

4.2.3 Compliance with the Code of Ethics (Annex A)

The candidate laboratory shall implement and comply with the provision(s) of the Code of Ethics. Candidate laboratories shall not conduct any anti-doping Analytical *Testing* activities for *Signatories* or *WADA* and shall not accept *Samples* directly from individual *Athletes* or from individuals or organizations acting on their behalf.

The Director of the candidate laboratory shall provide the Code of Ethics to all employees and ensure their understanding and compliance with all aspects of the Code of Ethics.

4.2.4 Laboratory Independence and Impartiality

As a condition to enter the probationary period, the candidate laboratory shall provide documentation to *WADA* demonstrating that, before obtaining *WADA* accreditation, they will comply with the requirements of Laboratory independence and impartiality indicated in Article 4.4.2.4.

4.2.5 Pre-Probationary Test and On-Site Assessment

Prior to entering the probationary period, *WADA* shall conduct a pre-probationary test (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.

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 Sections 6.0 and 7.0, respectively.

The candidate laboratory shall report the results for the PPT blind EQAS samples in *ADAMS* (in compliance with Article 6.3.1) within a period of twenty (20) 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*. Additional data may be required upon *WADA's* request. This documentation shall be submitted within ten (10) 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.

After receiving the PPT EQAS results, *WADA* shall inform the candidate laboratory of the evaluation of its performance and provide guidance for improvement. Corrective actions, if any, shall be conducted and reported by the candidate laboratory to *WADA* within thirty (30) days, or as otherwise indicated by *WADA*.

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) 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.

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.

Upon satisfactory completion of the candidate laboratory requirements (as per Article 4.2), as determined by the LabEG, a candidate laboratory enters the probationary phase of *WADA* accreditation as a "*WADA* probationary laboratory".

4.3 Probationary Laboratory for *WADA* Accreditation

4.3.1 Participating in the *WADA* EQAS Program

During the probationary period, the laboratory shall successfully analyze at least fifteen (15) blind EQAS samples, distributed over multiple EQAS rounds within a period of twelve (12) months (see Section 6.0 for a description of the EQAS). During this period, *WADA* shall provide feedback to assist the probationary laboratory to improve the quality of its Analytical *Testing* process.

The probationary laboratory shall successfully report the results for the blind EQAS samples to *WADA* in accordance with Article 6.3.1 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 Sections 6.0 and 7.0, respectively.

4.3.2 Planning and Implementing Research and Development Activities

The probationary laboratory shall develop a plan for its research and development activities in the field of anti-doping science, for the initial three (3)-year period after obtaining *WADA* accreditation, allocating at least 7% of the operational annual budget expected from activities associated with *Signatories*.

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

[Comment: 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.]

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.

4.3.3 Planning and Implementing Sharing of Knowledge

During the probationary period, the probationary laboratory shall demonstrate its willingness and ability to collaborate and share knowledge with other Laboratories. A description of this sharing of knowledge is provided in the Code of Ethics (Annex A).

4.3.4 Compliance with the Code of Ethics (Annex A)

The probationary laboratory shall implement and comply with the provision(s) of the Code of Ethics. Probationary laboratories shall not conduct any anti-doping Analytical *Testing* activities for *Signatories* or *WADA* and shall not accept *Samples* directly from individual *Athletes* or from individuals or organizations acting on their behalf.

The Director of the probationary laboratory shall provide the Code of Ethics to all

employees and ensure their understanding and compliance with all aspects of the Code of Ethics.

4.3.5 Obtaining ISO/IEC 17025 Accreditation by the Laboratory

Before *WADA* grants accreditation, the probationary laboratory shall obtain ISO/IEC 17025 accreditation from an Accreditation Body, with primary reference to the interpretation and application of the ISO/IEC 17025 requirements to the analysis of *Samples* (see Section 5.0). 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 Management System according to the requirements of ISO/IEC 17025 applicable to the analysis of *Samples* (see Section 5.0). Based on this, the laboratory shall initiate and prepare for the accreditation process by consulting with an Accreditation Body. The probationary laboratory shall correct and document any identified nonconformities with the ISO/IEC 17025 standard within the defined timelines.

The Accreditation Body should send a summary of the Assessment Report and any corrective/preventive action documentation addressing nonconformities, in English or French, to *WADA*. Should the probationary laboratory prefer to send the information directly to *WADA*, the laboratory shall do so within a reasonable 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.

4.3.6 Analytical *Testing* Procedures

Before *WADA* grants accreditation, probationary laboratories shall provide documentation to *WADA* demonstrating that all mandatory Test Methods (*e.g.* GC/C/IRMS, hGH, GHRF and EPO methods) have been validated and included in the Laboratory's Scope of ISO/IEC 17025 accreditation.

4.3.7 Laboratory Independence and Impartiality

Before *WADA* grants accreditation, probationary laboratories shall provide documentation to *WADA* demonstrating compliance with the requirements of Laboratory independence and impartiality established in Article 4.4.2.4.

4.3.8 Professional Liability Insurance Coverage

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

4.4 *WADA*-Accredited Laboratory

4.4.1 Obtaining *WADA* accreditation

4.4.1.1 *WADA* Accreditation Assessment - Final Accreditation Test

Once *WADA* has determined that the laboratory has successfully completed the requirements of the probationary period, 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*. At *WADA*'s discretion, the FAT and on-site assessment may be conducted separately or at the same time. Representative(s) of the Accreditation Body may be invited as observers to the *WADA* on-site assessment.

As part of the FAT, the probationary laboratory shall analyze a minimum of fifteen (15) blind EQAS samples. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in Sections 6.0 and 7.0, respectively.

Compliance with the defined requirements in the Application of ISO/IEC 17025 to the analysis of *Samples*, the ISL and other *WADA* Laboratory standards (*Technical Documents*, Technical Letters, Laboratory Guidelines), and the practice and documentation of the laboratory will be assessed. The FAT shall assess both the scientific competence and the capability of the probationary laboratory to manage multiple *Sample*s.

Costs associated with the *WADA* on-site assessment and FAT shall be at the probationary laboratory's expense.

The probationary laboratory shall successfully report the results for the blind EQAS samples in the FAT to *WADA* in accordance with Article 6.3.1 within seven (7) 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) 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.

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) days, or as otherwise indicated by *WADA*.

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) days, or as otherwise indicated by *WADA*. The nonconformities identified in the FAT EQAS and the Assessment Report shall be satisfactorily addressed by the laboratory and the recommendations for improvement should be implemented before accreditation can be granted.

4.4.1.2 *WADA* Recommendation for Accreditation

Based on the relevant documentation received from the probationary laboratory, the Assessment Report(s) from *WADA* and from the relevant Accreditation Body, the LabEG shall evaluate the probationary laboratory's progress in meeting all the requirements outlined in Articles 4.3 and 4.4.1.1.

Once all accreditation requirements have been satisfactorily met by the probationary laboratory, the LabEG will submit its recommendation that the laboratory be granted *WADA* accreditation to the *WADA* Executive Committee for approval.

However, if following the FAT and on-site assessment, and the 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 any pending nonconformity(-ies). The provision of documentation, the analysis of additional EQAS samples and/or an additional assessment (on-site, remotely or as a documentary audit, as determined by *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 Article 4.2 or to re-start the probationary phase of accreditation in accordance with Article 4.3.

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.

4.4.1.3 Issuing and Publishing of *WADA* Accreditation Certificate

An Accreditation Certificate signed by a duly authorized representative of *WADA* shall be issued in recognition of the *WADA* accreditation. Such Accreditation Certificate shall specify the name of the Laboratory and the period for which the Accreditation Certificate is valid. Accreditation

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

4.4.2 Maintaining *WADA* Accreditation

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

4.4.2.1 Maintain ISO/IEC 17025 Accreditation

The Laboratory shall maintain accreditation to ISO/IEC 17025, with primary reference to the analysis of *Samples* (Section 5.0), granted by a relevant Accreditation Body, which is an ILAC full member and signatory to the ILAC MRA for testing activities as defined in ISO/IEC 17025.

4.4.2.2 Flexible Scope of ISO/IEC 17025 Accreditation [3]

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

[Comment: 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.]

The Laboratories are not eligible to apply a Flexible Scope of ISO/IEC 17025 Accreditation to the analysis of *Samples* in 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 providing approval. Before applying such a new Analytical *Testing* Procedure to the analysis of *Samples,* a

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

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

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.

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

Laboratory to provide method validation documentation or EQAS performance data in support of that *Adverse Analytical Finding*.

[Comment: Laboratories shall not apply a WADA-specific Analytical Testing Procedure to the analysis of Samples until such method is included in the Laboratory's Scope of ISO/IEC 17025 Accreditation.]

4.4.2.3 Participate in the *WADA* EQAS Program

Laboratories are required to participate in the *WADA* EQAS on a continuous basis and meet the performance requirements of the EQAS as described in Section 6.0.

4.4.2.4 Laboratory Independence and Impartiality

The Laboratory shall be administratively and operationally independent from any organization that could exert undue pressure on the Laboratory and affect the impartial execution of its tasks and operations [4].

In order to be administratively independent, the Laboratory cannot be administered by, connected or subject to an *Anti-Doping Organization,* sport organization or government Ministry of Sport or other government body responsible for sport performance, including their Board Members, staff, Commission Members or officials. This is necessary to avoid potential conflicts of interest and ensure full confidence in the Laboratory's competence, impartiality, judgment and operational integrity, in compliance with ISO/IEC 17025.

In order to be operationally independent, the Laboratory shall manage its own affairs without hindrance, interference or direction from any *Person*. The Laboratory shall, without limitation, control: the allocation of its budget, the procurement of equipment and other resources, Laboratory personnel decisions, the research conducted by the Laboratory and all *Sample* Analytical *Testing* and reporting of results.

The Laboratory shall 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.*

[4] Laboratories shall comply with these requirements of administrative and operational independence by 1 January 2022, unless otherwise approved by *WADA*.

university, hospital, public institution), *Anti-Doping Organizations*, sport organizations, government, or other sponsors, while following applicable accounting regulations in connection with the receipt and management of those funds.

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

4.4.2.5 Document 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, signed by the Laboratory Director. All staff employed at the Laboratory, permanent or temporary, shall also read, agree to and sign the Code of Ethics. The Laboratory may be asked to provide documentation of compliance with the provisions of the Code of Ethics.

The Laboratory shall establish a system requiring Laboratory staff to report any alleged breaches of the Code of Ethics to the Laboratory Director, which the Laboratory Director shall report to *WADA*. However, if Laboratory staff suspect that the Laboratory Director may have breached the Code of Ethics, the Laboratory staff shall report the alleged breaches of the Code of Ethics directly to *WADA*. The Laboratory Director and/or the Laboratory's host organization and/or *WADA*, as applicable, 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 and/or the Laboratory's host organization 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 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 anti-doping science, including an annual budget in this area of at least 7% of the total annual operational budget allocated to activities associated with *Signatories*.

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 (2) years). 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].

[Comment: 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 supply an annual progress report to *WADA* documenting research and development results in the field of anti-doping science. The Laboratory shall also relate research and development plans for the following year.

4.4.2.7 Document Implemented Sharing of Knowledge

The Laboratory shall demonstrate its willingness and ability to share knowledge with other Laboratories. The Laboratory shall disseminate the results of its research and development activities to other Laboratories. The Laboratory 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 other Laboratories to *WADA*. A description of sharing of knowledge is provided in the Code of Ethics (Annex A).

4.4.2.8 Maintain Professional Liability Insurance Coverage

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

4.4.2.9 Providing renewed letter(s) of support

Letter(s) of support, as described in Article 4.1.3, from *Signatories* shall be provided to *WADA* every two (2) years confirming three (3) years of support or unless otherwise approved by *WADA.*

4.4.2.10 Maintain Minimum Number of *Samples*

In order to maintain proficiency in Analytical *Testing*, Laboratories are required to analyze a minimum of 3,000 *Samples* provided annually by *Code*-compliant *Anti-Doping Organizations* (as determined by *WADA*) or as otherwise approved by *WADA*.

[Comment: 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 will monitor the number of *Samples* tested by the Laboratory. If the number of *Samples* falls below 3,000 per year, the Laboratory's *WADA* accreditation may be suspended in accordance with Article 4.6.4.1.2.

It is recognized that specific circumstances may affect a Laboratory's ability to analyze a minimum of 3,000 *Samples* annually, such as when an *Anti-Doping Organization* is declared non-compliant with the *Code* by *WADA*, or when the Laboratory is not operational for the full calendar year. In such cases, *WADA* shall require that the Laboratory implement measures to maintain proficiency in Analytical *Testing*, for example by strengthening its internal Quality Assurance Scheme (iQAS) and internal audits program. *WADA* may also provide additional EQAS samples and/or conduct a documentary audit and/or an on-site or remote (on-line) assessment, at its discretion, in order to assess the status of the Laboratory's operations.

4.4.2.11 Publication of Laboratory Analytical *Testing* Procedures, services and fees

Laboratories shall report and maintain in *ADAMS* an up-to-date list of Analytical *Testing* Procedures and services, including standard prices, to assist *Anti-Doping Organizations* in developing Test Distribution Plans. Upon request by an *Anti-Doping Organization*, Laboratories should cooperate with the *Anti-Doping Organization* by providing other relevant information regarding *Testing* plans (*e.g.* Laboratory analytical capabilities).

4.4.2.12 Participating in *WADA* / Accreditation Body Re-assessments and Continuous Assessments during the Accreditation Cycle

- Accreditation Body Re-assessment and/or Continuous Assessment during the Accreditation Cycle

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

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

  The Laboratory shall provide *WADA* with an updated copy of the ISO/IEC 17025 Certificate and Scope of ISO/IEC 17025 Accreditation as soon as it is obtained from the Accreditation Body.

- *WADA* Laboratory Assessment

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

  As part of an announced or unannounced Laboratory assessment, *WADA* retains the right to request copies of Laboratory documentation and/or request Further Analysis of selected "A" and/or "B" *Samples* either on-site or in a Laboratory(-ies) chosen by *WADA*.

4.5 Removal of *Samples* by *WADA*

4.5.1 Removal of *Samples* for Analysis or Further Analysis

Within the context of an investigation or Laboratory performance monitoring activity (for example, during an on-site *WADA* Laboratory assessment), *WADA*, initially at its expense, may remove *Sample(s)* from a Laboratory in order to conduct Further Analysis, or analysis of the *Sample* if the analytical results for that *Sample* have not yet been reported, for the purpose described in *Code* Article 6.2. In such cases, *WADA* shall notify the *Testing* Authority, which shall retain ownership of the *Sample(s)* pursuant to the Article 10.1 of the *International Standard* for *Testing* and Investigations (ISTI). Notwithstanding the aforementioned, *WADA* shall retain the right to request analysis or Further Analysis, at its expense, as permitted by *Code* Article 6.6.

[Comment: 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 analysis or Further Analysis of the Samples from the Laboratory.]

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).

In connection with its monitoring of Laboratory performance, *WADA* may direct Further Analysis of a *Sample* which has resulted in a *Code* Article 2.1 anti-doping rule violation charge without consent of the *Athlete* or approval from a hearing body as provided in *Code* Article 6.5, provided that the analytical result from that Further Analysis cannot be used against the *Athlete* (for example, re-analysis of *Samples* which a Laboratory

has reported as *Adverse Analytical Findings* when the Laboratory has been determined to have reported False *Adverse Analytical Findings* using the same Analytical Method).

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 Article 5.3.12, for purposes of Laboratory quality assurance and education, including the implementation of a system of transfer of *Samples* reported as Negative Findings between Laboratories. In this regard, the number of *Samples* directed by *WADA* for re-analysis may vary.

[Comment: A transfer of Samples with Negative Findings shall apply only to Samples collected by Signatories.]

4.6 *WADA* Monitoring of Accreditation Status

WADA shall regularly review the compliance of Laboratories 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 Analytical *Testing* issues reported to *WADA* by stakeholders to assess the overall performance of each Laboratory and to decide its accreditation status.

4.6.1 Maintenance of *WADA* Accreditation

Compliance with all the requirements established in Article 4.4.2, including satisfactory performance by a Laboratory in the EQAS and in routine Analytical *Testing* (see Sections 6.0 and 7.0), as determined by *WADA*, is a critical requirement for the maintenance of the Laboratory's *WADA* accreditation.

4.6.2 Re-accreditation Costs

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

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.

4.6.4 Withdrawal of *WADA* Accreditation

A Laboratory's *WADA* accreditation may be suspended or revoked, or subject to an Analytical *Testing* Restriction, whenever the Laboratory fails to comply with the ISL and/or *Technical Documents* and/or Technical Letters, or where the Suspension, Revocation 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.

The imposition of an Analytical *Testing* Restriction or the Suspension of a Laboratory's *WADA* accreditation should not imply the automatic withdrawal of its ISO/IEC 17025 accreditation. The status of the Laboratory's ISO/IEC 17025 accreditation is to be independently assessed by the relevant Accreditation Body.

4.6.4.1 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*.

The Laboratory's *WADA* accreditation shall be subject to a Suspension and not to an Analytical *Testing* Restriction, as determined by the LabEG, when the sanction imposed to the Laboratory impacts Analytical Methods or target Analytes that are included in the Laboratory's standard *In-Competition* or *Out-of-Competition* Analytical *Testing* menus, because it would affect the analysis of all respective urine and/or blood *Samples* received by the Laboratory.

[Comment: If WADA determines that the noncompliance(s) leading to the Suspension of the Laboratory's WADA accreditation or to 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.]

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 Points Scale Table in Article 7.3), or if a Laboratory has reported a False *Adverse Analytical Finding* with *Consequences* for an *Athlete*, the LabEG shall make a recommendation to the Chairman of the *WADA* Executive Committee that the Laboratory be subject to an Analytical *Testing* Restriction,

Suspension or Revocation, as applicable and as determined by the LabEG.

If the LabEG recommends to the Chairman of the *WADA* Executive Committee that the Laboratory be subject to an Analytical *Testing* Restriction or Suspension when the specific above-mentioned nonconformities are present, the Laboratory may not challenge the recommendation of the LabEG before the Disciplinary Committee pursuant to Article 4.6.4.5 at any time. However, in the event that the Chairman of the *WADA* Executive Committee imposes an Analytical *Testing* Restriction or a Suspension against the Laboratory pursuant to this Article 4.6.4.1.1, the Laboratory may appeal the decision of the Chairman of the *WADA* Executive Committee to *CAS* in accordance with Article 4.6.4.7.

Notwithstanding the above, if the LabEG recommends the Revocation of a Laboratory's *WADA* accreditation in situations where the Laboratory has accumulated the maximum allowed number of penalty points for the EQAS and/or Analytical *Testing* (as determined by the application of the Points Scale Table in Article 7.3) or where the Laboratory reports a False *Adverse Analytical Finding* that results in *Consequences* for an *Athlete*, the Laboratory may challenge the LabEG's recommendation before the Disciplinary Committee in accordance with Article 4.6.4.5.

4.6.4.1.2 Analytical *Testing* Restriction and Suspension or Revocation of Accreditation – Disciplinary Proceedings.

The LabEG may also recommend to the Chairman of the *WADA* Executive Committee that a Laboratory be subject to an Analytical *Testing* Restriction or a Suspension or Revocation of its *WADA* accreditation even if the Laboratory has not reported a False *Adverse Analytical Finding* with *Consequences* for an *Athlete* or has not attained the maximum number of penalty points detailed in the Points Scale Table in Article 7.3, but where the Laboratory's other Analytical *Testing* failure(s) and/or other identified nonconformities (as described in Articles 4.6.4.2 and 4.6.4.3, as applicable) otherwise justifies that such action be taken to ensure the full reliability and accuracy of Analytical *Testing* and the accurate reporting of test results.

Prior to commencing disciplinary proceedings in accordance with Article 4.6.4.5, and if requested by the Laboratory, the LabEG shall hold a resolution facilitation session with the Laboratory as described in Article 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 Article 4.6.4.4, the

Chairman of the *WADA* Executive Committee must approve any agreement between the Laboratory and the LabEG 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 terms for the Analytical *Testing* Restriction or Suspension following the resolution facilitation process, as per Article 4.6.4.4, the Laboratory may challenge the LabEG's recommendation to the Disciplinary Committee and disciplinary proceedings will be conducted in accordance with Article 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 subject to an immediate Provisional Suspension pending the outcome of the disciplinary proceedings. In such cases, a decision by the Chairman of the *WADA* Executive Committee to impose a Provisional Suspension 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 subject to a Provisional Suspension, the proceedings before the Disciplinary Committee should be conducted within forty-five (45) days of the date when the provisional Analytical *Testing* Restriction or the Provisional Suspension of the Laboratory's *WADA* accreditation was imposed.

4.6.4.2 Noncompliances with the ISL

Noncompliances with the ISL that may lead to an Analytical *Testing* Restriction or Suspension include, but are not limited to:

- Suspension, or withdrawal of ISO/IEC 17025 accreditation;
- Failure to establish and/or maintain administrative and operational independence as described in Article 4.4.2.4;
- Repeated reporting of False *Adverse Analytical Findings* and/or False Negative Findings:

  [Comment: 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.]

- The reporting of two (2) or more independent [5] False *Adverse Analytical Findings* per EQAS round; or
- The reporting of three (3) or more independent [5] *False Adverse Analytical Findings*, including EQAS and routine Analytical *Testing*, per twelve (12)-month period; or
- The reporting of three (3) or more independent [5] False Negative Findings per EQAS round; or
- The reporting of four (4) or more independent [5] False Negative Findings, including EQAS and routine Analytical *Testing*, per twelve (12)-month period; or
- Any combination of four (4) or more independent [5] False *Adverse Analytical Findings* and False Negative Findings, including EQAS and routine Analytical *Testing*, per twelve (12)-month period.

- Failure to implement a *Technical Document* or Technical Letter by the effective date without prior approval by *WADA*;
- 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 Article 5.3.8.4);
- Failure to take appropriate corrective action after an unsatisfactory performance during routine Analytical *Testing* or in a blind EQAS or double-blind EQAS round;
- Failure to take appropriate corrective action for ISL and/or *Technical Document* and/or Technical Letter noncompliance(s) identified from *WADA* Laboratory assessment(s);
- Failure to cooperate with *WADA* or the relevant *Testing* Authority or *Results Management* Authority in providing documentation;
- Noncompliance(s) with the Code of Ethics;
- Laboratory staff and/or management issues, including but not limited to:

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

- Major changes in 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 Articles 5.2.2.3 and 5.2.2.4);
- 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 Article 4.4.2.10; or
- Failure to cooperate in any *WADA* enquiry in relation to the activities of the Laboratory.

4.6.4.3 Revocation of Accreditation

The *WADA* Executive Committee shall revoke the *WADA* accreditation of any Laboratory 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.

The LabEG shall recommend the Revocation of a Laboratory's *WADA* accreditation 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*;

  [Comment: The repeated reporting of False Adverse Analytical Findings with Consequences for an Athlete(s) shall lead to the Revocation of the Laboratory's WADA accreditation, irrespective of whether or not those findings were independent as described in Article 4.6.4.2.]

- 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;

- 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 Article 4.6.6.1;
- Repeated failure to comply with the ISL and/or *Technical Documents* and/or Technical Letters;
- Serious Laboratory noncompliance(s) with the ISL and/or *Technical Documents* and/or Technical Letters identified, for example, during *WADA* Laboratory assessments, by documented client complaints or through other enquiries 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;
- Repeated failure to take appropriate corrective action following ISL and/or *Technical Document* and/or Technical Letter noncompliance(s) identified from *WADA* Laboratory assessment(s);
- Repeated failure to analyze the minimum number of *Samples* indicated in Article 4.4.2.10;
- 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 any relevant *Testing* Authority or *Results Management* Authority during a period of 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 that is determined by *WADA* to impact the operations of the Laboratory;
- Repeated and/or continuous failure to cooperate in any *WADA* inquiry in relation to the activities of the Laboratory;
- Failure to establish and/or maintain administrative and operational independence, as described in Article 4.4.2.4, during the Suspension period;
- Loss of support which significantly affects the quality and/or viability of the

Laboratory; and

- Any other cause that materially affects the ability of the Laboratory to ensure the full reliability and accuracy of Analytical *Testing* and the accurate reporting of test results.

If the Laboratory does not accept the LabEG's recommendation for Revocation either following the resolution facilitation session (if held pursuant to Article 4.6.4.4) or otherwise, the LabEG shall recommend to the Chairman of the *WADA* Executive Committee that the Laboratory's *WADA* accreditation be immediately subject to a Provisional Suspension pending the outcome of the disciplinary proceedings conducted pursuant to Article 4.6.4.5.

In such cases, a decision by the Chairman of the *WADA* Executive Committee to impose a Provisional Suspension against the Laboratory shall not be subject to appeal by the Laboratory. However, should the Laboratory be immediately subject to a Provisional Suspension, the proceedings before the Disciplinary Committee should be conducted within forty-five (45) days of the date when the Provisional Suspension of the Laboratory's *WADA* accreditation was imposed.

4.6.4.4 Resolution Facilitation

Prior to the commencement of Disciplinary Proceedings in accordance with Articles 4.6.4.1.2, 4.6.4.3 and 4.6.4.5, the 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 LabEG.

During the resolution facilitation session, the Laboratory and the LabEG may come to an agreement regarding the Laboratory's Revocation or the terms and duration of the Suspension of the Laboratory's *WADA* accreditation or 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 conducted in accordance with Article 4.6.4.5.

If the Laboratory and the LabEG are unable to come to an agreement regarding the Laboratory's Revocation or the terms and duration of the Suspension of the Laboratory's *WADA* accreditation or the Laboratory's Analytical *Testing* Restriction during the resolution facilitation session, the procedure indicated in Article 4.6.4.5 shall be followed.

In the case of a LabEG recommendation for Revocation, a resolution facilitation session shall not be available to a Laboratory which is already serving a Suspension or Analytical *Testing* Restriction.

4.6.4.5 Disciplinary Proceedings

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

In such circumstances, *WADA* shall provide the DC with the 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 Article 3 of the Procedural Rules (Annex C).

The DC shall issue a recommendation to the Chair of the *WADA* Executive Committee or, where applicable (*e.g.* in the case of a Revocation), 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 Article 7 of the Procedural Rules (Annex C).

[Comment: For the avoidance of doubt, and as indicated in Article 4.6.4.1.1, disciplinary proceedings will not be conducted pursuant to Article 4.6.4.5 in situations where 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 Points Scale Table in Article 7.3), or if a Laboratory has reported a False Adverse Analytical Finding with Consequence(s) for an Athlete. Instead, and only in the aforementioned circumstances, the Laboratory may appeal any decision of the Chairman of the WADA Executive Committee to impose an Analytical Testing Restriction or to suspend the Laboratory's WADA accreditation directly to CAS in accordance with Article 4.6.4.7.]

4.6.4.6 Notification of Decision

Upon completion of the procedures indicated in Articles 4.6.4.5 or 7.3, as applicable, and in accordance with the timelines indicated in Article 7 of the Procedural Rules (Annex C), *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:

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 Article 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 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* Article 13.7. The Laboratory shall have twenty-one (21) days from the date of receipt of the decision from *WADA* to file an appeal to *CAS*.

4.6.4.8 Public Notice

WADA shall publicly announce a change in a Laboratory's accreditation status on its website as soon as the Laboratory is notified by *WADA* of its decision. 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 Article 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 when the Laboratory's *WADA* accreditation is reinstated following a Suspension or when an Analytical *Testing* Restriction is lifted.

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, which are not included in the standard Analytical *Testing* menu for *In-Competition* or *Out-of-Competition Samples* received by the Laboratory, *WADA* may impose an Analytical *Testing* Restriction for that class of *Prohibited Substance(s)* or *Prohibited Method(s)* or for the specific Analytical *Testing* Procedure in which the noncompliance(s) occurred.

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 Article 5.2.6. 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 transfer [6] 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*

[6] 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) days of being notified of the Analytical *Testing* Restriction decision. All associated costs shall be borne by the Laboratory under Analytical *Testing* Restriction.

Finding (as requested by *WADA*);

- *Samples*, which had been opened and were undergoing analysis for the Initial *Testing* Procedure(s) at the time of the Analytical *Testing* Restriction decision;
- *Samples* for which, at the time of the Analytical *Testing* Restriction decision, Initial *Testing* Procedure(s) had been completed and had produced Presumptive *Adverse Analytical Findings* requiring Confirmation Procedures, or *Samples* that are the subject of other Confirmation Procedures (*e.g.* GC/C/IRMS analysis for *Markers* of the steroid profile);
- *Samples* for which the "A" or "B" Confirmation Procedures had been completed, but results of the analysis had not been reported by the Analytical *Testing* Restriction date, or *Samples* which were undergoing "A" or "B" Confirmation Procedures at the time of the imposition of the Analytical *Testing* Restriction;
- *Samples* which had been reported as *Adverse Analytical Findings* based on the "A" Confirmation Procedure prior to the imposition of the Analytical *Testing* Restriction. These *Samples* shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions. Should a "B" Confirmation Procedure be requested during the period of the Analytical *Testing* Restriction, both "A" and "B" *Samples* shall be transferred [6] 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 was caused by the reporting of False Negative Finding(s), and further investigation reveals that other Negative Finding(s) had been reported for *Samples* that are still stored in the Laboratory, the Laboratory shall inform the *Testing* Authority and *WADA*. In such cases, both the "A" and "B" containers of the relevant *Samples* shall be transferred [6] 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* or to the Analytical *Testing* Procedure(s) that were associated with the Negative Finding(s), as determined by *WADA.*

4.6.5.2 Suspension

A Laboratory whose *WADA* accreditation has been suspended is ineligible to perform Analytical *Testing* of *Samples* for any *Signatory*. 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*.

- Suspension for Violation of the Code of Ethics

  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 [7] all *Samples* (both the "A" and "B" *Samples*) in the Laboratory's custody to other Laboratory(-ies) chosen by the *Testing* Authority(-ies).

- Suspension for Reporting of False *Adverse Analytical Finding(s)*

  If the reason for the Suspension was related to the reporting of False *Adverse Analytical Finding(s)*, all Analytical *Testing* shall cease immediately. In addition, the Laboratory shall transfer [7] 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 (as requested by *WADA*);
  - *Samples* for which, at the time of the Suspension decision, Initial *Testing* Procedure(s) had been completed and had produced Presumptive *Adverse Analytical Findings* requiring Confirmation Procedures, or *Samples* that are the subject of other Confirmation Procedures (*e.g.* GC/C/IRMS analysis for *Markers* of the steroid profile);
  - *Samples*, which had been opened and were undergoing analysis for the Initial *Testing* Procedure(s) at the time of the Suspension;
  - *Samples* which had been received at the Laboratory but had not been opened at the time of the Suspension [these *Samples* shall be kept sealed in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions until transfer [7] to another

[7] 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) 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.

Laboratory(-ies)].

- *Samples* for which "A" or "B" Confirmation Procedures had been completed, but results of the *analysis* had not been reported by the Suspension date, or *Samples* which were undergoing "A" or "B" Confirmation Procedures at the time of the Suspension;
- *Samples* which had been reported as *Adverse Analytical Findings* based on the "A" Confirmation Procedure prior to the Suspension.

- Suspension for Other Reasons

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

- *Samples* which had been analyzed and reported as a Negative Finding, and which have either been stored in the Laboratory for a period of less than three (3) months or have been placed in long-term storage upon request by the *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 was caused by the reporting of False Negative Finding(s), and further investigation reveals that other Negative Finding(s) had been reported by the Laboratory, the Laboratory shall inform the *Testing* Authority and *WADA*. In such cases, both the "A" and "B" containers of the relevant *Samples* shall be transferred [7] 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) produced Presumptive *Adverse Analytical Finding(s)* or other Confirmation Procedures were required (*e.g.* GC/C/IRMS analysis for *Markers* of the steroid profile), both the "A" and "B" *Samples* shall be transferred [7] to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.

In addition, if the Suspension was caused by the reporting of False Negative Finding(s) and the Initial *Testing* Procedure(s) had produced negative results, both the "A" and "B" *Samples* shall also be transferred [7] 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 had 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 had 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 produced a Presumptive *Adverse Analytical Finding*, both the "A" and "B" *Samples* shall be transferred [7] to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.

  If the Suspension was caused by the reporting of False Negative Finding(s), then the Laboratory shall cease all Analytical *Testing* and have the "A" and "B" *Samples* transferred [7] to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.

- *Samples* which had been received at the Laboratory but had not been

opened yet at the time of the Suspension:

These *Samples* shall be kept sealed in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until transfer [7] 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 were undergoing "A" or "B" Confirmation Procedures at the time of the Suspension:

  Both the "A" and "B" *Samples* shall be transferred [7] to another Laboratory(-ies) for the repetition of the "A" and, if applicable, the "B" Confirmation Procedures.

- *Samples* which had 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 [7] 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 Suspension concerns the analysis of blood *Samples* for the *ABP*, *Samples* collected prior to the Suspension date may be analyzed by the Laboratory. The reporting of results for the relevant *Sample(s)* in *ADAMS* shall include a comment regarding the Suspension at the time of analysis so that the *Testing* Authority (or *Results Management* Authority, if different) / APMU can take this information into account during the *Results Management* process.

[Comment: 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.]

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 a Laboratory 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 or approval for the *ABP* has been revoked is ineligible to perform Analytical *Testing* of *Samples* for any *Testing* Authority. The Laboratory Internal Chain of Custody maintained by a revoked laboratory for stored *Samples* is valid until such time that arrangements can be

made, in consultation with *WADA*, for the transfer [7] of relevant *Samples* to a Laboratory(-ies).

A laboratory whose *WADA* accreditation or approval for the *ABP* has been revoked shall arrange the transfer [7] of *Samples* in the laboratory's custody to a Laboratory(-ies) chosen by the *Testing* Authority or *WADA*, respectively, within thirty (30) 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*. 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*.

[Comment: The revoked laboratory shall transfer all Samples in its custody for which the Analytical Testing process has not been completed at the time of the Revocation. The Testing Authority may also choose to transfer additional Samples retained in the laboratory in accordance with Articles 5.3.11.1. or 5.3.11.2, or other Samples for which it is the owner pursuant to Article 10.1 of the ISTI and that had been analyzed and were 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 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.

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 a *WADA* Laboratory 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 an additional six (6) months, if the Laboratory provides justifiable explanation(s) for the delay, as determined by the LabEG, in addressing the conditions to lift the Suspension or Analytical *Testing* Restriction (including the submission of 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 the Laboratory is subject to Revocation proceedings in accordance with Article 4.6.5.3 or as otherwise determined by *WADA*.

If applicable, a delay in the delivery of the ISO/IEC 17025 accreditation to the Laboratory by the relevant Accreditation Body may also constitute grounds to extend the Suspension of the Laboratory's *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 Article 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 LabEG shall recommend the Revocation of the Laboratory's accreditation. The decision to revoke a Laboratory's *WADA* accreditation shall be rendered by the *WADA* Executive Committee.

If the Laboratory is subject to Revocation proceedings either at the end of a six (6) month Suspension or Analytical *Testing* Restriction or at the end of a Suspension or Analytical *Testing* Restriction that has been extended to twelve (12) months, the Laboratory's *WADA* accreditation shall remain subject to the Suspension or Analytical *Testing* Restriction, as applicable, until the

completion of the Revocation proceedings and pending the decision of the *WADA* Executive Committee regarding the Revocation of the Laboratory's *WADA* accreditation. If the *WADA* Executive Committee confirms the Revocation of the Laboratory's *WADA* accreditation, then the Laboratory's *WADA* accreditation shall remain subject to the Suspension or Analytical *Testing* Restriction, as applicable, until the Revocation comes into effect according to Article 4.6.4.7.

[Comment: For Revocation proceedings conducted at the end of a Suspension or Analytical Testing Restriction period, no resolution facilitation session, as described in Article 4.6.4.4, will be conducted.]

WADA shall not be required to take any other formal action to extend the Laboratory's Analytical *Testing* Restriction or Suspension beyond either the initial six (6)- month Suspension or Analytical *Testing* Restriction or beyond the end of the Suspension or Analytical *Testing* Restriction that has been extended to twelve (12) months, apart from formally instituting Revocation proceedings against the Laboratory. Further, if Revocation proceedings are instituted against a Laboratory in such circumstances, the Laboratory may not appeal the extension of its Analytical *Testing* Restriction or Suspension beyond the initial six (6)- month Suspension or Analytical *Testing* Restriction period or beyond the end of the Suspension or Analytical *Testing* Restriction that has been extended to twelve (12) months.

WADA will notify the Laboratory of the decision of the *WADA* Executive Committee to revoke the Laboratory's *WADA* accreditation in accordance with Article 4.6.4.6.

The Laboratory may appeal *WADA*'s decision to revoke its *WADA* accreditation in accordance with Article 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 must apply for *WADA* accreditation as a new laboratory in accordance with Article 4.1.

When seeking a new *WADA* accreditation, the laboratory may request that *WADA* expedite the laboratory re-accreditation procedure, which 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" as justification for modifying the requirements of Articles 4.1 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 whether such modifications are justified, and which steps must be followed prior to granting approval to the laboratory to enter the probationary phase of accreditation.

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 Articles 4.6.5.2 (temporary closure) or 4.6.5.3 (permanent closure).

If a Laboratory voluntarily ceases its anti-doping Analytical *Testing* operations on a temporary basis, the Laboratory shall maintain satisfactory performance in the analysis of EQAS samples during the period of inactivity. The period of temporary cessation of Analytical *Testing* activities shall not exceed six (6) months, with one possible extension of up to six (6) months (as determined by the Chair of the *WADA* Executive Committee based on a recommendation from the LabEG). If the Laboratory is unable to resume its Analytical *Testing* operations within a twelve (12)- month period, the *WADA* Executive Committee shall revoke the Laboratory's accreditation, unless otherwise approved by *WADA*.

If a 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*.

4.7 Process and Requirements for *WADA* Laboratory Approval 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 Article describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining *WADA* approval for the *ABP*.

4.7.1 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).

4.7.1.1 Expression of Interest

The applicant laboratory shall officially contact *WADA* in writing to express its interest in becoming an *ABP* Laboratory.

4.7.1.2 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.

4.7.1.3 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 *Signatory.* 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 *ABP* Laboratory is not a viable option for the *Signatory's ABP* program.

4.7.2 Candidate Laboratory for *WADA* Approval for the *ABP*

The application materials described in Articles 4.7.1.1 to 4.7.1.3 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.

4.7.2.1 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 of 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 Article 5.2.3);
    - 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 technical support (*e.g.* contract/access to instrument maintenance services);
- Status of the *ABP* method development and validation. Method validation report (if completed);
- Status of ISO/IEC 17025 or ISO 15189 accreditation;
- Status of Laboratory's independence and impartiality as described in ISL Article 4.7.2.2;
- 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.

WADA may require an update of this documentation during the process of the *ABP* approval.

[Comment: Candidate laboratories for ABP approval are encouraged to establish agreement(s) with a Laboratory(-ies) for mentoring and training in order to ensure successful preparation towards obtaining the WADA approval.]

4.7.2.2 Laboratory Independence and Impartiality [8]

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.

- Administrative independence requires that the laboratory be a separate legal entity, or a defined part of a legal entity, without any administrative links to an *Anti-Doping Organization* or any other sport organization or government Ministry of Sport or other government body responsible for sport performance (see Article 4.4.2.4);
- Operational independence requires that the laboratory shall manage its *ABP* Analytical *Testing* activities without hindrance, interference or direction from any *Person*.

4.7.2.3 Compliance with the Code of Ethics (Annex A)

The candidate laboratory shall implement and comply with the provision(s) of the Code of Ethics. A letter of compliance with the Code of Ethics shall be signed by the laboratory Director and provided to *WADA*.

4.7.2.4 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.

4.7.2.5 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 for testing laboratories according to ISO/IEC 17025 or for medical laboratories according to ISO 15189.

The laboratory shall correct and document any identified nonconformities with the ISO/IEC 17025 or ISO 15189 requirements within defined timelines. The

[8] *ABP* Laboratories shall comply with these requirements of administrative and operational independence by 1 January 2022, unless otherwise approved by *WADA*.

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.

4.7.2.6 *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.

[Comment: At WADA's discretion, the initial on-site assessment for the ABP approval may not be necessary or may be conducted on-line or as a document-based audit, in cases of previously accredited or WADA-approved laboratories].

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) 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 an *ABP* Laboratory. 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.

4.7.2.7 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.

4.7.3 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 an *ABP* Laboratory.

4.7.3.1 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.

On an annual basis, if approval for the *ABP* is maintained, the *ABP* Laboratory shall receive a renewed *WADA* Approval Certificate signed by a duly authorized representative of *WADA* (exclusive to Analytical *Testing* in support of the Hematological Module of the *ABP*), which is issued in recognition of such approval.

The *WADA* Approval Certificate shall specify the name of the *ABP* Laboratory 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 *ABP* Laboratories shall be maintained on *WADA*'s website and in *ADAMS* for stakeholder reference.

4.7.4 Maintaining Status as an *ABP* Laboratory

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

- 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 Section 5.0 relevant to the analysis of blood *Samples*;
- Documented compliance with the Code of Ethics (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 Internal Chain of Custody (TD LCOC);

- Production of Laboratory Documentation Packages or Certificates of Analysis for the Blood *ABP* in compliance with the *Technical Document* on Laboratory Documentation Packages (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*.

4.7.4.1 Suspension or Revocation of *WADA* approval for the *ABP*

A laboratory's *WADA* approval for the *ABP* may be suspended or revoked whenever the *ABP* Laboratory 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* (including notice, publication, and right to appeal) shall be conducted in accordance with the procedures described in Articles 4.6.4 and 4.6.5, applied and modified accordingly, and the Procedural Rules found in Annex C of the ISL.

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

5.1 Introduction and Scope

This section of the ISL is intended as an extension of the application of ISO/IEC 17025 to the field of *Doping Control*. Any aspect of Analytical *Testing* or management not specifically discussed in this document or in the relevant *Technical Documents*, Technical Letters or Laboratory Guidelines shall be governed by ISO/IEC 17025 (or ISO 15189, as applicable for *ABP* Laboratories). The application focuses on the specific parts of the processes that are critical with regard to the quality of the laboratory's performance as a Laboratory or *ABP* Laboratory, and are therefore significant in the evaluation and accreditation process.

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

- 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.

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

5.2.2 Laboratory Personnel

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.

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.

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.

Specific criteria shall be met by the Laboratory Director, Laboratory Quality Manager, Laboratory Certifying Scientists, and Laboratory Supervisory Personnel, as outlined below.

5.2.2.1 Laboratory Director

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

The Laboratory Director shall be a full-time appointment and his/her 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; or
- In the absence of a Doctoral degree, a postgraduate degree (*e.g.* Master's degree) in one of the natural sciences and appropriate anti-doping science experience and training (*e.g.* a senior Laboratory position for a minimum of five (5) years), including the documented ability to develop analytical methodology and oversee research projects; or
- In the absence of a postgraduate degree, a Bachelor degree in one of the natural sciences 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;
- Demonstrated working 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*. *WADA* reserves the right to review the credentials of such appointment and either approve it or reject it in accordance with the above qualifications.

5.2.2.2 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 a Bachelor 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.

5.2.2.3 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 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 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 degree for this position;
- Appropriate training and experience (*e.g.* three (3) years or more) including 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 *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.

5.2.2.4 Laboratory Supervisory Personnel

The Laboratory shall have qualified personnel to serve as Laboratory Supervisors. All Laboratory Supervisors shall have a thorough understanding of the Laboratory's Management System including the review, interpretation and reporting of test results, the maintenance of Laboratory Internal Chain of Custody, and proper implementation of corrective and preventive actions in response to analytical problems.

The qualifications for a Laboratory Supervisor shall include:

- At least a Bachelor 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 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 Facilities and Environmental Conditions

5.2.3.1 Laboratory Facilities

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:

- 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);
- 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;
- 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.

- The Laboratory shall have a dedicated and restricted area within the Controlled Zone for *Sample* receipt and Aliquot preparation;

  Access to the Laboratory's *Sample* receipt and Aliquot preparation area shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.

- The Laboratory shall have a dedicated and restricted *Sample* storage area;

Access to stored *Samples* [9] shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.

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, to another Laboratory, or to another Fit-for-Purpose facility under the responsibility of the *Testing* Authority, which has ownership of the *Sample(s)* pursuant to Article 10.1 of the ISTI. Long-term storage facilities shall maintain security requirements comparable to the security requirements applicable to a Laboratory's short-term storage of *Samples*. If the external *Sample* storage facility is not covered by the Laboratory's ISO/IEC 17025 accreditation, then the subcontracted external storage facility shall have its own ISO accreditation or accredited certification (*e.g.* 17025, 20387, 9001). The transfer of the *Samples* to the long-term storage facility shall be recorded.

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

[9] 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.

5.2.3.2 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;
- Expected date(s) of assessment of the new facilities by the Accreditation Body (evidence of continued accreditation and/or acceptance of suitability of the new Laboratory facilities required when made available by the Accreditation Body);
- New Laboratory contact information and coordinates;
- Assessment of the effect of the Laboratory relocation on client operations.

5.2.3.3 Environmental Control

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

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

The Laboratory shall:

- Ensure appropriate electrical service (for example, by provision of an alternative power supply such as an UPS system and/or power generators) and environmental conditions (space, temperature, humidity, as applicable) for all Laboratory instrumentation and equipment critical to Laboratory operations, such that service is not likely to be interrupted;
- Have policies in place to ensure the integrity of refrigerated and/or frozen stored *Samples* in the event of an electrical or freezer/refrigerator equipment failure.

5.2.3.4 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 outside 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 *Persons* or recovered after disposal (for example, bottles should be destroyed, or trash containers should be properly secured).

5.2.3.5 Control and Security of Electronic Data and Information

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

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

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

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

The Laboratory shall utilize a secure data storage system that prevents unauthorized access and data loss (*e.g.* failed hard drive, fire, flooding). The Laboratory shall ensure that at least two (2) independent, regularly backed-up copies of all relevant analytical/LIMS/instrument software files are available.

- If the Laboratory is utilizing a non-cloud-based system, then at least one (1) backup copy shall be stored in a restricted and secure environment either in the Laboratory (*e.g.* fire and waterproof safe) or in a secure off-site location (*e.g.* in a mirrored server that guarantees the integrity of the server and the stored data);
- If the Laboratory is using a cloud-based system, the Laboratory data shall be, at a minimum, replicated in two different physical locations (*e.g.* between two different availability zones within the same region or between different regions) in order to minimize the possibility of data loss.

The software utilized by the Laboratory shall prevent the changing of data and test results, unless there is a system to record the change with audit trail capabilities which is limited to users with authorized access. The audit trail shall

record the *Person* performing the editing task, the date and time of the edit, the reason(s) for the change to the original data and allow the retention of the original data.

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

5.2.4 Laboratory Equipment

The Laboratory shall have access to equipment that is required for the correct performance of Analytical *Testing* activities. The Laboratory shall maintain sufficient instrumental capacity to minimize the risk of operational delays and meet the analytical and results reporting obligations of the ISL and its related *Technical Documents*, Technical Letters and Laboratory Guidelines. A list of available equipment shall be established and maintained.

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

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.

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

Qualified vendors may be contracted to service, maintain, and repair equipment. All maintenance, service, and repair of equipment shall be recorded.

5.2.5 Metrological Traceability

5.2.5.1 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 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.

5.2.5.2 Reference Collections

Samples or isolates may be obtained from *in vitro* or *in vivo* sources [*e.g.* (i) an external quality control sample, (ii) an isolate from a urine or blood sample after an authenticated administration, or (iii) an "*in-vitro*" incubation with liver cells, microsomes or biological fluids] and be used as Reference Collections.

Reference Collections shall be traceable to a *Prohibited Substance* or a *Prohibited Method*, and the analytical data shall be sufficient to establish the identity of the Analyte.

5.2.6 Subcontracting of Analysis

A Laboratory or *ABP* Laboratory shall perform all work with qualified personnel and equipment within its accredited or approved facility, respectively.

A Laboratory may subcontract an analysis to another Laboratory, in consultation with the *Testing* Authority. The conditions that justify subcontracting include, for example:

- A specific technology or Analyte(s) that are not within the Laboratory's Scope of ISO/IEC 17025 Accreditation;
- An Analytical *Testing* Restriction decision;
- Other justifications such as a need for higher sensitivity or specific equipment or expertise, temporary workload or technical incapacity);
- In exceptional circumstances, *WADA* may elect to grant specific authorization to subcontract analyses using specific methods to an ISO/IEC 17025-accredited laboratory approved by *WADA*, which has the necessary technique within its 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 Laboratory.

[Comment: Alternatively, the analysis may be 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(s) to the other Laboratory(-ies) or expert(s) as the case may be.]

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

Recommendations to facilitate the implementation of subcontracted analyses and Further Analysis are provided in the *WADA* Laboratory Guidelines on "Conducting and Reporting Subcontracted Analysis and Further Analysis for *Doping Control*".

5.2.7 Purchasing of Services and Supplies

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

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

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

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

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

5.3 Process Requirements

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

5.3.1 Reviewing of Requests, Tenders and Contracts

Review of legal documents or agreements related to Analytical *Testing* shall meet the requirements of ISO/IEC 17025.

5.3.2 Reception, Registration and Handling of *Samples*

The Laboratory may receive *Samples*, which have been collected, sealed and transported to the Laboratory according to the ISTI.

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

The *Sample* transport container shall be inspected, and any irregularities recorded.

Each individual *Sample* shall be inspected, and any irregularities recorded *(*see Article 5.3.3.1). However, *Samples* transferred for long-term storage purposes are not subject to an individual inspection by the receiving Laboratory until a *Sample* has been selected for Further Analysis.

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.

5.3.3 Acceptance of *Samples* for Analysis

The Laboratory shall analyze each *Sample* received, unless the *Sample* meets any of the following conditions:

- In cases where the Laboratory receives two (2) urine *Samples*, which are linked to a single *Sample* Collection Session from the same *Athlete* according to the *Doping Control* Forms (DCF), the Laboratory shall analyze both *Samples* collected, unless otherwise instructed by the *Testing* Authority;

  [Comment: 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).]

- 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 the subsequent collected *Sample* with the highest specific gravity (SG), as recorded on the DCF:

  [Comment: The Laboratory may conduct analyses on the additional collected Samples, if deemed necessary, with the agreement of the Testing Authority. The Laboratory may also combine Aliquots from multiple Samples, 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.]

- If the *Sample(s)* meet documented *Sample* rejection criteria, which have been agreed with the *Testing* Authority.

  [Comment: If justified by the Sample irregularities observed (see Article 5.3.3.1), the Laboratory shall seek instructions from the Testing Authority on the performance of Analytical Testing on the Sample. The Testing Authority shall inform the Laboratory in writing within seven (7) 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 Article 5.3.3.2, 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.]

- Except as provided in this Article 5.3.3, *Samples* shall not be accepted by a Laboratory for the sole purpose of being put into long-term storage or for later analysis without first being subject to an Analytical *Testing* Procedure.

5.3.3.1 *Samples* with Irregularities

With the exception of the situation when a large number of *Samples,* which have already been analyzed, are received for long-term storage only (*e.g.* from a *Major Event Organization*), as described in Article 5.3.11.3, the Laboratory shall observe and document conditions that exist at the time of *Sample* reception or registration that may adversely impact on the integrity of a *Sample* or on the performance of Analytical *Testing* Procedures. Only unusual conditions shall be recorded.

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

- *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 Analytical *Testing* menu, is not provided, *e.g.* missing or incomplete 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-evident device or not sealed upon receipt;
- *Sample* volume does not meet the Suitable Volume of Urine for Analysis or is otherwise inadequate to perform the requested Analytical *Testing* menu;
- 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* [10].

When an analysis on a *Sample* with documented irregularities is performed, the Laboratory shall record the irregularities in the Test Report.

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

5.3.3.2 *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 or has been broken; the *Sample*'s integrity has been compromised in any way; the *Sample* is heavily contaminated, the "A" or "B" *Sample* is missing), the Laboratory shall notify and seek authorization from the *Testing* Authority to split the other *Sample* container ("A" or "B", as applicable), provided that it is properly sealed. The *Testing* Authority shall inform the Laboratory of its decision in writing within seven (7) days of notification by the Laboratory. If the *Testing* Authority decides not to proceed with the *Sample* splitting procedure, then the Laboratory shall report the *Sample* as Not Analyzed in *ADAMS*, including the noted *Sample* irregularities and the documented reasons if provided by the *Testing* Authority.

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

The process of opening and splitting the *Sample* and resealing of the remaining second fraction shall be conducted in accordance with Article 5.3.6.2.3 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. When the *Athlete* cannot be located, does not respond or 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.

[Comment: If the Athlete chooses to witness the Sample splitting procedure, the Athlete takes responsibility for forfeiting his/her anonymity.]

When the splitting procedure concerns blood *Samples*, which have been collected for Analytical *Testing* on the blood serum/plasma fraction, the sealed, intact ("A" or "B") *Sample* shall be centrifuged as soon as practical after Laboratory reception to obtain the serum or plasma fraction. The centrifuged *Sample* shall be stored frozen in the sealed *Sample* collection tube according to established protocols until the *Sample* opening/splitting procedure can be conducted. The opening of the *Sample* for the splitting of the serum/plasma fraction and resealing of the second fraction shall be carried out as described immediately above.

5.3.4 Initial Storage and *Sample* Aliquoting for Analysis

It is recommended that the Laboratory assign specific staff member(s) to *Sample* aliquoting, and that the process of aliquoting is performed in a specifically designated area (see Article 5.2.3.1).

The Aliquot preparation procedure for any Initial *Testing* Procedure or Confirmation Procedure shall minimize the risk of contamination of the *Sample* or Aliquot. The Laboratory shall use new material(s) (*e.g.* new test tubes) to take Aliquots for Confirmation Procedures.

5.3.4.1 Urine *Samples*

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

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.

The Laboratory shall measure the pH and 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 measuring and reporting the steroid profile, TD EAAS).

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.

5.3.4.2 Blood *Samples*

The Laboratory shall follow the applicable *Technical Document(s),* Technical Letter(s) or Laboratory Guidelines for handling and storing blood *Samples*.

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

a) *Sample*s for which Analytical *Testing* will be performed on blood serum/plasma fraction only (not on cellular components).

   Blood *Samples* ("A" and "B" *Samples*), for which Analytical *Testing* will be

performed on the plasma/serum fraction only should be centrifuged as soon as practical after Laboratory reception to obtain the serum or plasma fraction [11].

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 collection tube according to established protocols until analysis, if applicable [11].

b) *Sample*s for which Analytical *Testing* will be performed on the cellular fraction 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, *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.

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.* EPO), then the plasma *Sample* shall be stored as described above.

5.3.5 Selection and Validation 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*.

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-

[11] Unless otherwise specified in a *Technical Document*, Technical Letter or Laboratory Guidelines.

for-Purpose and shall be approved at least by the Laboratory Director and the Laboratory Quality Manager, or other qualified senior Laboratory staff, *e.g.* the Deputy Scientific Director, as designated by the Laboratory Director.

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).

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

5.3.5.1 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.

a) Validation of Initial *Testing* Procedures for Non-Threshold Substances

The Laboratory shall validate the Selectivity, carryover, reliability of detection at the MRPL and Limit of Detection (LOD) for the Initial *Testing* Procedure from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis. For chromatographic-mass spectrometric Analytical Methods, the Initial *Testing* Procedure shall allow the detection of each Non-Threshold Substance or its representative *Metabolite(s)* or *Marker(s)* at 50% or less of the Minimum Required Performance Levels (MRPL) (see the *Technical Document* on Minimum Required Performance Levels, TD MRPL).

For Non-Threshold Substances with *Minimum Reporting Levels* (*MRL*), the Laboratory shall validate and document the concentration levels that will require a Confirmation Procedure.

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.

b) 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 the Analyte of interest, taking into account interference(s) from the matrix or from other substance(s) present in the *Sample*. Selectivity shall be determined and documented from the analysis of an adequate number of representative samples prepared in the matrix of *Sample* analysis, in compliance with the *Technical Document* on chromatographic-mass spectrometric identification criteria (TD IDCR) or other applicable *Technical Document*, Technical Letter or Laboratory Guidelines. The Confirmation Procedure shall be able to discriminate between Analytes 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 identified at no more than 5% false negative rate (in compliance with the TD IDCR or other applicable *Technical Document*, Technical Letter or Laboratory Guidelines). The LOI shall be lower than the applicable MRPL;

  [Comment: 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 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 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 Sample with low background or 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(s) or characteristic Marker(s)) 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.]

- 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;

  [Comment: Elimination of 'injection memory' effect is demonstrated by injecting a blank control sample for the Analyte in question, prepared in the Sample matrix, immediately prior to the Sample of interest.]

5.3.5.2 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, TD GH) or Laboratory Guidelines.

a) Validation of Initial *Testing* Procedures for Threshold Substances

The Laboratory shall validate Initial *Testing* Procedures that are Fit-for-Purpose, in accordance with relevant *Technical Document(s),* Technical Letter(s) or Laboratory Guidelines.

For chromatographic-mass spectrometric Initial *Testing* Procedures, the Laboratory shall validate the Selectivity, LOD and dynamic range from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis [12].

The Laboratory shall validate and document the concentration levels which will require quantitative Confirmation Procedure(s)[12].

[12] Unless otherwise specified in a *Technical Document*, Technical Letter or Laboratory Guidelines.

[Comment: In order to account for a possible underestimation of concentrations of Threshold Substances during non-quantitative Initial Testing Procedures, the Laboratory shall establish, and document in the Test Method's SOP, criteria (e.g. concentration levels), determined during the Initial Testing Procedure method validation, to evaluate initial results as Presumptive Adverse Analytical Findings and ensure that all potentially positive Samples are subjected to quantitative Confirmation Procedures.

Unless otherwise specified in a Technical Document, Technical Letter or Laboratory Guidelines, the Laboratory may also choose to forward all Samples containing an exogenous Threshold Substance to confirmation analysis, in order to ensure that all potential Presumptive Adverse Analytical Findings are subjected to Confirmation Procedure(s).]

The estimation of Measurement Uncertainty (MU) is not required during the validation of Initial *Testing* Procedures [12].

b) Validation of Confirmation Procedures for Threshold Substances

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

- Selectivity, LOI, Robustness, Carryover (see Article 5.3.5.1);
- 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 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 levels close to 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 levels close to 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* (TD DL) or other applicable *Technical Document* (*e.g.* TD GH), Technical Letter or Laboratory Guidelines. At least, MU at levels close to the Threshold shall be addressed during the validation of the quantitative Confirmation Procedure.

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.

5.3.6 *Sample* Analysis

Laboratories shall analyze *Samples* collected by *Anti-Doping Organizations* using *In-Competition* or *Out-of-Competition* Analytical *Testing* menus to detect the presence of *Prohibited Substances* or *Prohibited Methods* only (as defined in the *Prohibited List*). In addition, Laboratories may analyze *Samples* for the following, in which case the results of the analysis shall not be reported as an *Atypical Finding* or an *Adverse Analytical Finding*:

- Non-prohibited substances or methods that are included in the *WADA* Monitoring Program (see *Code* Article 4.5);
- Non-prohibited substances for results interpretation purposes (*e.g.* confounding factors of the "steroid profile", non-prohibited substances that share *Metabolite(s)* or degradation products with *Prohibited Substances*), if applicable;
- Non-prohibited substances or methods requested as part of a *Results Management* process by the *Results Management* Authority, a hearing body or *WADA*;
- Non-prohibited substances or methods requested by the *Testing* Authority as part of its safety code, code of conduct or other regulations (see comments to *Code* Articles 5.1 and 23.2.2); or
- Additional analyses for quality assurance/quality improvement/method development or research purposes, in accordance with the requirements indicated in Article 5.3.12.

[Comment: An Anti-Doping Organization has the discretion to apply anti-doping rules to an Athlete who is neither an International-Level Athlete nor a National-Level Athlete and may elect

to request that Samples collected from these Athletes are analyzed for less than the full menu of Prohibited Substances and Prohibited Methods. The Anti-Doping Organization is responsible for providing the Laboratory with the appropriate written justification for a reduced Testing menu.]

At minimum, all Laboratories are required to implement all mandatory Analytical *Testing* Procedures, 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*.

[Comment: 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 should 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 Samples, Testing Authorities may decide to request Analytical Testing for specific Prohibited Substances or Prohibited Methods 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. WADA will maintain the list of mandatory Analytical Methods for reference by the Anti-Doping Organizations.]

Analytical *Testing* Procedure(s) included in the Laboratory's Scope of ISO/IEC 17025 Accreditation shall be considered as Fit-for-Purpose and therefore the Laboratory shall not be required to provide method validation documentation 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 method validation documentation or EQAS performance data in support of an *Adverse Analytical Finding* (see Article 4.4.2.2).

Laboratories may, on their own initiative and prior to reporting a test result, apply additional Analytical *Testing* Procedures to analyze *Samples* for *Prohibited Substances* or *Prohibited Methods* not included in the standard Analytical *Testing* menu or in the *Technical Document* for sport-specific analysis (TD SSA), provided that the additional work is conducted at the Laboratory's expense and does not significantly affect the possibility to submit the *Sample*, as identified by the *Testing* Authority or *WADA*, to Further Analysis. Results from any such analysis shall be reported in *ADAMS* and have the same validity and *Consequences* as any other analytical result.

5.3.6.1 Application of Initial *Testing* Procedures

The objective of the Initial *Testing* Procedure is to obtain information about the potential presence of *Prohibited Substance(s)* or *Metabolite(s)* of *Prohibited Substance(s),* or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method.* Results from Initial *Testing* Procedure(s) can be included as part of longitudinal studies (*e.g.* endogenous steroid or hematological profiles), provided that the method is Fit-for-Purpose.

The Initial *Testing* Procedure(s) shall fulfil the following requirements:

- The Initial *Testing* Procedure shall be Fit-for-Purpose;
- The Initial *Testing* Procedure shall be performed on Aliquot(s) taken from the container identified as the "A" *Sample*;

  [Comment: 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 Article 5.3.3.2).]
- The Initial *Testing* Procedure shall be recorded, as part of the *Sample* (or *Sample* batch) record, each time it is conducted;
- All batches undergoing an Initial *Testing* Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis [13];
- The Initial *Testing* Procedures for Non-Threshold Substances shall include appropriate controls of representative substance(s) at or below the MRPL;
- The Initial *Testing* Procedures for Threshold Substances shall include appropriate controls close to the Threshold [14];
- Results from Initial *Testing* Procedures are not required to consider the associated MU [14];
- 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.

[13] Unless otherwise specified in a *Technical Document*, Technical Letter or Laboratory Guidelines.

5.3.6.2 Application of Confirmation Procedures

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

A Confirmation Procedure for a Non-Threshold Substance with a *Minimum Reporting Level* may also be performed if the result estimated from the Initial *Testing* Procedure is lower than the applicable *Minimum Reporting Level*, as determined by the Laboratory in accordance with the method's validation results.

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* [14]. A Confirmation Procedure may also be performed if the result obtained in the Initial *Testing* Procedure is lower than the Threshold, as determined by the Laboratory or as specifically required by the *Testing* Authority (or *Results Management* Authority, if different) or *WADA*.

Irregularities in the Initial *Testing* Procedure(s) shall not invalidate an *Adverse Analytical Finding*, which is adequately established by a Confirmation Procedure.

The Confirmation Procedure(s) shall fulfil the following requirements:

- The Confirmation Procedure(s) shall be Fit-for-Purpose, including the estimation of the MU associated with a quantitative Confirmation Procedure;
- The Confirmation Procedure(s) shall be recorded, as part of the *Sample* (or *Sample* batch) record, each time it is conducted;
- The Confirmation Procedure shall have equal or greater Selectivity than the Initial *Testing* Procedure and shall provide accurate quantification results (applicable to Threshold Substances). The Confirmation Procedure should incorporate, when possible and adequate, a different *Sample* extraction protocol and/or a different analytical methodology [14];
- All batches undergoing a Confirmation Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis.

5.3.6.2.1 Confirmation Procedure Methods

Mass spectrometry (MS) coupled to chromatographic separation (*e.g.* gas or liquid chromatography) is the analytical technique of choice for confirmation of most *Prohibited Substances*, *Metabolite(s)* of a

[14] Unless otherwise specified in a *Technical Document*, Technical Letter or Laboratory Guidelines

Prohibited Substance, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method*. These are acceptable methods for both the Initial *Testing* Procedure and the Confirmation Procedure.

Affinity-binding assays (*e.g.* Immunoassays), electrophoretic methods and other Analytical Methods are also routinely used for detection of macromolecules in *Samples*.

[Affinity-binding assays applied for the Initial *Testing* Procedure(s) and Confirmation Procedure(s) 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, that any such purification or separation method is Fit-for-Purpose.

In affinity-binding assays which include multiple affinity reagents (such as sandwich immunoassays), 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. The other affinity reagent may be used in both affinity-binding assays.

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. 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*.]

5.3.6.2.2 "A" Confirmation Procedure:

- Aliquots

  The "A" Confirmation Procedure shall be performed using new Aliquot(s) taken from the container identified as the "A" *Sample*. At this point, the link between the *Sample* external code as shown in the *Sample* container and the Laboratory internal *Sample* code shall be verified.

  [Comment: 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 Article 5.3.3.2).]

- Target Analyte(s)

  If the presence of more than one (1) *Prohibited Substance*, *Metabolite(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* is detected by the Initial *Testing* Procedure(s), the Laboratory shall confirm as many of the Presumptive *Adverse Analytical Findings* as reasonably possible (such decision should take into account the volumes available in the "A" and "B" *Samples*). The confirmation(s) shall prioritize the identification and/or quantification of the *Prohibited Substance(s)* or *Prohibited Method(s)* that carry the longest potential period of *Ineligibility*. The decision shall be made in consultation with the *Testing* Authority (or *Results Management* Authority, if different) and documented.

- Existence of approved *Therapeutic Use Exemption* (*TUE*)

  When there is a Presumptive *Adverse Analytical Finding* for hCG, hGH (Biomarkers Test), Beta-2 Agonists, Diuretics, Amfetamine, Methylphenidate, Glucocorticoids or Beta-blockers, the Laboratory may contact the *Testing* Authority (or *Results Management* Authority, if different) to enquire whether an approved *Therapeutic Use Exemption* (*TUE*) exists for the *Prohibited Substance(s)* detected.

  [Comment: Unless there is a prior agreement between the Testing Authority (or Results Management Authority, if different) and the Laboratory, contacting the Testing Authority (or Results Management Authority, if different) in such cases is not a requirement for the Laboratory. The Laboratory may proceed, at its discretion, to confirm the Presumptive Adverse Analytical Finding for hCG, hGH (Biomarkers Test), Beta-2 Agonists, Diuretics, Amfetamine, Methylphenidate, Glucocorticoids or Beta-blockers and report an Adverse Analytical Finding in ADAMS according to the confirmation results obtained.]

[Comment: 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 permitted up to a maximum dose by inhalation only, as specified in the Prohibited List. 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.]

When possible, the Laboratory should provide an estimated concentration of the Analyte(s) from the Initial *Testing* Procedure. Any such contact with the *Testing* Authority (or *Results Management* Authority, if different) shall be confirmed in writing (for further guidance, refer to the Laboratory Guidelines on *TUE* enquiries).

The instruction by the *Testing* Authority (or *Results Management* Authority, if different) 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 (or *Results Management* Authority, if different) shall provide *WADA* with a copy of the approved *TUE* or the associated *TUE* number if the *TUE* has been submitted into *ADAMS*.

- Repetition of the "A" Confirmation Procedure

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

- "A" Confirmation Procedure for Non-Threshold Substances

  For Non-Threshold Substances without *Minimum Reporting Levels*, *Adverse Analytical Finding* or *Atypical Finding* decisions for the "A" *Sample* shall be based on the identification of the Non-Threshold Substance or its characteristic *Metabolite(s)* or *Marker(s)*, as applicable, in compliance with the TD IDCR and/or other relevant *Technical Document* (*e.g.* TD MRPL), Technical Letter or Laboratory Guidelines.

  For Non-Threshold Substances with *Minimum Reporting Levels* as specified in the TD MRPL, *Adverse Analytical Finding* decisions for the "A" *Sample* should be based on the identification of the Non-Threshold Substance or its characteristic *Metabolite(s)* or *Marker(s),* in compliance with the TD IDCR, at an estimated concentration greater than the *Minimum Reporting Level*, unless there is

justification for reporting the finding at levels below the *Minimum Reporting Level* (*e.g.* if the analysis forms part of an ongoing investigation).

- "A" Confirmation Procedure for Threshold Substances

  For Threshold Substances, *Adverse Analytical Finding* or *Atypical Finding* decisions for the "A" *Sample* shall be based on the confirmed identification (in accordance with the TD 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.

  Quantitative Confirmation Procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (*e.g.* concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) "A" *Sample* Aliquots [15]. If there is not enough *Sample* volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

  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).

  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* 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* 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

[15] Unless otherwise specified in a *Technical Document*, Technical Letter or Laboratory Guidelines.

if detected in the presence of any *Prohibited Substance* classified under 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*.

5.3.6.2.3 "B" Confirmation Procedure

- *Testing* Laboratory

  The "B" Confirmation Procedure shall be performed in the same Laboratory as the "A" Confirmation Procedure, unless there are exceptional circumstances, as determined by *WADA* and with *WADA*'s prior written approval, which prevent the "B" Confirmation Procedure from being performed in the same Laboratory.

- Notification and Timing of "B" Confirmation Procedure

  The "B" Confirmation Procedure shall only be performed by the Laboratory upon request by either the *Athlete* or the *Testing* Authority or *Results Management* Authority (if different).

  The *Testing* Authority or *Results Management* Authority, as applicable, should inform the Laboratory, in writing, within fifteen (15) days following the reporting of an "A" *Sample Adverse Analytical Finding* by the Laboratory, whether the "B" Confirmation Procedure shall be conducted. This includes situations when the *Athlete* does not request the "B" *Sample* analysis or expressly or implicitly waives his/her right to the analysis of the "B" *Sample*, but the *Testing* Authority or *Results Management* Authority decides that the "B" Confirmation Procedure shall still be performed.

  If the "B" Confirmation Procedure is to be performed, either upon the request of the *Athlete* or the *Testing* Authority or *Results Management* Authority, it should be performed as soon as possible after the *Testing* Authority or *Results Management* Authority, as applicable, has provided such notice to the Laboratory.

  The timing of the "B" Confirmation Procedure may be strictly fixed within a very short period of time and without any possible postponement, if circumstances so justify it. This can notably and without limitation be the case when a postponement of the "B" *Sample* analysis could significantly increase the risk of *Sample* degradation and/or inadequately delay the decision-making

process in the given circumstances (*e.g.* and without limitation, during or in view of a Major *Event* requiring rapid completion of the *Sample* analysis).

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 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 claims not to be available on the date or at the time of the opening of the "B" *Sample*, despite reasonable attempts to find an alternative date and time convenient both to the *Athlete* and to the Laboratory, the *Testing* Authority or *Results Management* Authority or *WADA*, as applicable, shall instruct the Laboratory to proceed regardless. The Laboratory, in consultation with the *Testing* Authority, the *Results Management* Authority or *WADA*, as applicable, shall 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 *Sample* collection documentation. An Independent Witness may be appointed even if the *Athlete* has indicated that he/she will be present and/or represented.

- Authorization of non-Laboratory *Persons* to attend the "B" Confirmation Procedure

  The following non-Laboratory *Persons* shall be authorized to attend the "B" Confirmation Procedure:

  - The *Athlete* and/or representative(s) of the *Athlete* or, in the absence of the *Athlete* and/or representative(s), an Independent Witness:

    - The *Athlete* and a maximum of two (2) representatives, and/or the Independent Witness, have the right to attend the "B" *Sample* opening, aliquoting and resealing procedures;

    - The *Athlete* and/or one (1) representative may also have reasonable opportunity to observe other steps of the "B" 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.

      [Comment: An Independent Witness may also attend even if the Athlete is present and/or represented.]

  - 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 the *National Olympic Committee* and/or National Sport Federation and/or International Federation, as applicable, may also attend the "B" *Sample* opening procedure, upon request and with prior approval of the Laboratory Director.

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 may have any *Person* removed, including the *Athlete* or *Athlete's* representative, if they are not following the instructions, disturbing or interfering with the "B" *Sample* opening or the Analytical *Testing* process. Any behavior resulting in removal shall be reported to the *Testing* Authority and/or *Results Management* Authority, as applicable. Interference may further be constitutive of an anti-doping rule violation in accordance with *Code* Article 2.5, "*Tampering*, or *Attempted Tampering* with any part of *Doping Control* by an *Athlete* or other *Person*".

- Opening, Aliquoting and Resealing of "B" *Sample*

The "B" Confirmation Procedure shall be performed using Aliquot(s) taken from the container defined as the "B" *Sample*.

[Comment: In cases when the "B" Sample cannot be used for Analytical Testing, the unopened, sealed "A" Sample may be split (see Article 5.3.3.2) 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 *Athlete* and/or his/her representative(s) or the Independent Witness shall verify that the "B" *Sample* container is properly sealed and shows no signs of *Tampering*, and that the identifying numbers match that on the *Sample* collection documentation. At a minimum, the Laboratory Director or representative and the *Athlete* or their representative(s) and/or the Independent Witness shall sign the Laboratory documentation attesting that the "B" *Sample* container was properly sealed and showed no signs of *Tampering*, and that the identifying numbers matched those on the *Sample* collection documentation.

If the *Athlete*, and/or their representative(s), or the Independent Witness refuse to sign the Laboratory documentation because they consider that the "B" *Sample* container was not properly sealed and/or showed signs of *Tampering*, or if the identifying numbers did not match those on the *Sample* collection documentation, the Laboratory shall not proceed with the "B" Confirmation Procedure and will inform the *Testing* Authority or *Results Management* Authority (if different) immediately to obtain instructions. In such cases, the "B" Confirmation Procedure may have to be re-scheduled.

If, on the other hand, the *Athlete* and/or their representative(s), or the Independent Witness refuse to sign the Laboratory documentation for any other reason, the Laboratory shall proceed with the "B" Confirmation Procedure. At the same time, the Laboratory shall inform the *Testing* Authority or *Results Management* Authority (if different) immediately. The reasons for the refusal shall be documented and included as a comment in the Test Report in *ADAMS*.

The Laboratory shall then ensure that the "B" *Sample* container is opened and Aliquots for the "B" Confirmation Procedure are taken in the presence of the *Athlete* or his/her representative(s) or the Independent Witness.

The Laboratory shall also ensure that, after opening and taking Aliquots for the "B" Confirmation Procedure, the "B" *Sample* is properly resealed in the presence of the *Athlete* and/or his/her representative(s) or the Independent Witness, who should be offered the opportunity to select the resealing equipment for the "B" *Sample* container from several identical/sealed items, if available.

At a minimum, the Laboratory Director or representative and the *Athlete* and/or their representative(s) and/or the Independent Witness shall sign another part of the Laboratory documentation attesting that they have witnessed the "B" *Sample* opening and aliquoting procedures and that the "B" *Sample* was properly resealed. If the *Athlete* and/or their representative or the Independent Witness refuse to sign this part of the Laboratory documentation, the reasons for the refusal shall be documented and included as a comment in the Test Report in *ADAMS*. In either case, the Laboratory shall continue with the "B" Confirmation Procedure.

- Target Analyte(s)

  If more than one (1) *Prohibited Substance*, *Metabolite(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* has been confirmed in the "A" Confirmation Procedure, the Laboratory shall confirm as many of the *Adverse Analytical Findings* as possible given the "B" *Sample* volume available. The decision on the prioritization for the confirmation(s) shall be made to prioritize the analysis of the *Prohibited Substance(s)* or *Prohibited Method(s)* that carry the longest potential period of *Ineligibility*. The decision should be made in consultation with the *Testing* Authority (or *Results Management* Authority, if different) and documented.

- Repetition of the "B" Confirmation Procedure

  The Laboratory may repeat the Confirmation Procedure for a "B" *Sample,* if appropriate, (*e.g.* quality control failure, chromatographic peak interferences, inconclusive "B" confirmation results). In that case, the previous test result shall be nullified. The Laboratory may repeat the "B" Confirmation Procedure using the remaining volume of the same Aliquot initially taken from the "B" *Sample* container. However, if there is not enough volume left of the initial Aliquot, then the Laboratory shall use a new Aliquot(s) taken from the re-sealed B" *Sample* container. In such cases, the re-opening, aliquoting and re-sealing of the B" *Sample* container shall be performed in the presence of the *Athlete* and/or *Athlete*'s representative(s) and/or Independent Witness, as per the procedure described above. Each Aliquot used shall be documented.

- "B" Confirmation with Negative Results

  If the final "B" confirmation results are negative, the Analytical *Testing* result shall be considered a Negative Finding. The Laboratory shall notify the *Testing* Authority (or *Results Management* Authority, if different) and *WADA* immediately. The Laboratory shall conduct an internal investigation of the causes of the discrepancy between the "A" and "B" *Sample* results and should report its outcomes to the *Results Management* Authority and *WADA* within seven (7) days.

  [Comment: Target Analytes [e.g. parent compound, Metabolite(s), Maker(s)] used to conclude the presence of a given Prohibited Substance or Use of a Prohibited Method may differ between the "A" and "B" Confirmation Procedures. This does not mean that the "B" confirmation results are negative, as long as the Analyte(s) targeted

allows the unequivocal and conclusive identification of the Prohibited Substance or Prohibited Method in the "B" Sample.]

- "B" Confirmation Procedure for Non-Threshold Substances and exogenous Threshold Substances

  For Non-Threshold Substances (including those with *Minimum Reporting Levels* as specified in the TD MRPL) and exogenous Threshold Substances, the "B" *Sample* results shall only confirm the presence of the *Prohibited Substance(s)* or its *Metabolite(s)* or *Marker(s)* identified in the "A" *Sample* (in compliance with the TD IDCR) for the *Adverse Analytical Finding* to be valid [16]. No quantification or estimation of concentrations of such *Prohibited Substance*, or its *Metabolite(s)* or *Marker(s)* is necessary.

- "B" Confirmation Procedure for endogenous Threshold Substances

  For endogenous Threshold Substances, *Adverse Analytical 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. Comparison of the measured value of the "B" *Sample* to the measured value of the "A" *Sample* is not necessary to establish "B" *Sample* confirmation. The "B" *Sample* value is only required to exceed the applicable Threshold.

  Quantitative "B" Confirmation Procedures for endogenous Threshold Substances shall be based on the determination of the mean of measured analytical values (*e.g.* concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) "B" *Sample* Aliquots [16]. 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

[16] Unless otherwise specified in a *Technical Document*, Technical Letter or Laboratory Guidelines.

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).*

5.3.6.3 Further Analysis

Further Analysis of stored *Samples* shall, as a matter of principle, be aimed at detecting all the *Prohibited Substance(s)* or *Metabolite(s)* of *Prohibited Substance(s),* or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* included in the *Prohibited List* in force at the time of the collection of the *Sample(s).*

- Selection of *Samples* and Laboratories for Further Analysis

  Stored *Samples* may be selected for Further Analysis at the discretion of the *Testing* Authority. *WADA* may also direct the Further Analysis of *Samples* at its own expense (see *Code* Article 6.6). In cases where *WADA* takes physical possession of a *Sample(s)*, it shall notify the *Testing* Authority (see *Code* Article 6.8), which shall retain ownership of the *Sample(s)* pursuant to the ISTI Article 10.1, unless ownership of the *Sample(s)* has been transferred pursuant to ISTI Article 10.2.

  The choice of which Laboratory will conduct the Further Analysis will be made by the *Testing* Authority or *WADA*, as applicable. Requests to the Laboratory for Further Analysis shall be made in writing and be recorded as part of the *Sample*'s documentation.

  When a *Sample* has been reported as a Negative Finding or *Atypical Finding*, there is no limitation on the *Testing* Authority or *WADA* or others authorized by either of them to conduct Further Analysis on the *Sample*.

  Further Analysis may also be performed on stored *Samples*, which were previously reported as *Adverse Analytical Findings* where such report did not result in an anti-doping rule violation charge under *Code* Article 2.1. Any *Prohibited Substance* or *Prohibited Method* detected, which was prohibited at the time of *Sample* collection, shall be reported.

  However, pursuant to *Code* Article 6.5, Further Analysis may not be applied on a *Sample* after the responsible *Anti-Doping Organization* has charged the *Athlete* with a *Code* Article 2.1 anti-doping rule violation resulting from the analysis of the *Sample*, without the consent of the *Athlete* or approval from a hearing body.

Previously acquired Initial *Testing* Procedure data may also be re-evaluated for the presence of *Prohibited Substances* or their *Metabolite(s)* or *Marker(s)* of *Prohibited Substances* or *Prohibited Methods*, at the initiative of the *Testing* Authority, the *Results Management* Authority, *WADA* 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.

- Analytical *Testing* Procedures for Further Analysis of Stored *Samples*

  Further Analysis of stored *Samples* shall be performed under the ISL, *Technical Documents*, Technical Letters and Laboratory Guidelines in effect at the time the Further Analysis is performed.

  Further Analysis of stored *Samples* includes, notably, but without limitation, the application of newly developed or more sensitive Analytical *Testing* Procedures and/or the analysis of new target Analytes of *Prohibited Substance(s)* or *Prohibited Method(s)* [*e.g. Metabolite(s)* and/or *Marker(s)*], which were not known or not included in the initial Analytical *Testing* of the *Sample*.

  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).

- Further Analysis of Stored *Samples* Process

  a) 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" Confirmation Procedure shall be applicable (as per Article 5.3.6.2.3).

b) 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 Article 5.3.3.2. 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*, which shall be deemed as the "A" *Sample*. 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 Article 5.3.6.2.3.

[Comment: 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).]

5.3.6.4 Alternative Biological Matrices

Any 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).

5.3.7 Assuring the Validity of Analytical Results

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

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

- Use of appropriate quality control samples (QCs)

  [Comment: Appropriate positive and negative QCs shall be included in every analytical run

both for the Initial Testing Procedure(s) and Confirmation Procedure(s) [17].

Appropriate internal standard(s) shall be used for chromatographic 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).]

- Implementation of an Internal Quality Assurance Scheme (iQAS)

  [Comment: The Laboratory shall establish a functional and robust iQAS program, in accordance with the requirements of ISO/IEC 17025, which challenges the entire scope of the Analytical Testing process (i.e. from Sample accessioning through result reporting). The Laboratory shall implement a procedure that prevents the submission of iQAS results into ADAMS.

  The iQAS plan shall include and evaluate as many Laboratory procedures as possible, including the submission of a sufficient number of test samples on a regular basis (e.g. monthly) and shall incorporate as many categories of Prohibited Substances and Prohibited Methods as possible.

  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).]

- Mandatory participation in the *WADA* EQAS (see Section 6.0).

  - Implementation of Internal Audits

    [Comment: Internal audits shall be conducted in accordance with the requirements of ISO/IEC 17025, and shall have a dedicated SOP incorporating a detailed procedure for the planning and performance of the audits, the training and selection of internal auditors, specification of their auditing activities, as well as for management of the internal audit conclusions (reviewing and follow-up of nonconformities).

    Internal audit responsibilities may be shared amongst personnel provided that any Laboratory staff member 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.]

  - Implementation of External Audits

    [Comment: Laboratories may also consider having their procedures and systems audited by other Laboratory Directors or external auditors. However, this shall not replace the performance of internal audits by the Laboratory.]

[17] Unless otherwise specified in a *Technical Document*, Technical Letter or Laboratory Guidelines.

5.3.8 *Results Management*

5.3.8.1 Review of Results

The Laboratory shall conduct a minimum of two (2) independent reviews of all Initial *Testing* Procedure raw data and results. The review process shall be recorded.

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

- Second Opinion

  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 *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 the recent obtaining of *WADA* accreditation or after a period of Suspension or Analytical *Testing* Restriction), or requested at the discretion of the Laboratory (*e.g.* for firstly detected Analytes or for difficult to interpret findings). In any case, the request for a second opinion shall be made in writing and the second opinion received shall be recorded as part of the *Sample*'s documentation. Any transfer of data and information necessary for the second opinion shall be made securely and respecting the confidentiality of the analytical data and any other information.

  The Laboratory that performed the analysis is responsible for the result and for issuing the final Test Report.

- Laboratory Review of *Adverse Analytical Findings* and *Atypical Findings*

  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;
  - Initial *Testing* Procedure(s) and Confirmation Procedure(s) analytical data and calculations;
  - Quality control data;
  - Completeness of technical and analytical documentation supporting the reported findings;

- Compliance of test data with the Analytical *Testing* Procedure's validation results (*e.g.* MU);
- Assessment of the existence of significant data or information that would cast doubt on or refute the Laboratory findings;

  [Comment: 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.]

- When the Confirmation Procedure result(s) are rejected as *Adverse Analytical Finding(s)* or *Atypical Finding(s)* based on the results review, the reason(s) for the rejection shall be recorded.

5.3.8.2 Traceability of Results and Documentation

The Laboratory shall have documented procedures to ensure that it maintains a record related to each *Sample* analyzed. In the case of an *Adverse Analytical Finding* or *Atypical Finding*, the record shall include the data necessary to support the conclusions reported as set forth in and limited by the TD LDOC.

- Each step of Analytical *Testing* shall be traceable to the staff member who performed that step;
- Significant deviation from a written SOP shall be recorded;
- Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record;
- Requests for information by the *Testing* Authority, *Results Management* Authority or *WADA* to a Laboratory shall be made in writing;
- Laboratory Documentation Packages and Certificates of Analysis shall be in compliance with the TD LDOC. Laboratories are not required to produce a Laboratory Documentation Package for a *Sample* in which no *Prohibited Substance* or *Prohibited Method* or their *Metabolite(s)* or *Marker(s)* was detected, unless requested by a hearing body or disciplinary panel as part of a *Results Management* process or Laboratory disciplinary proceedings.

5.3.8.3 Confidentiality of the Analytical Data and *Athlete's* Identity

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). The Laboratory shall not make any attempt to identify an *Athlete* that has provided a *Sample*.

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

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. Whenever the Laboratory handles analytical data or information where an *Athlete* is identified or identifiable, the Laboratory shall treat such data in accordance with the requirements of the *International Standard* for the Protection of Privacy and Personal Information (ISPPPI).

5.3.8.4 Reporting Test Results

A Laboratory shall not conduct any additional Analytical *Testing* on a *Sample* for which the *Athlete* has been charged with a *Code* Article 2.1 anti-doping rule violation unless consent from the *Athlete* or approval from a hearing body is obtained by the *Testing* Authority or *Results Management* Authority (if different) – see also Article 5.3.6.3.

Unless specifically requested to make a partial submission of test results by the *Testing* Authority or *Results Management* Authority (if different), a Laboratory shall not report analytical results for any *Sample* until all analyses detailed in the Analytical *Testing* menu of the relevant DCF have been completed (*e.g*. ongoing analysis for EPO). Therefore:

a) If a Laboratory is requested to report an *Adverse Analytical Finding(s)* for a *Sample(s)* before all analyses on that *Sample* have been completed, then the Laboratory shall advise the *Testing* Authority or *Results Management* Authority (if different) that *Sample* analysis has not been completed and, in addition, that if the *Athlete* is charged with a *Code* Article 2.1 anti-doping rule violation before the additional analyses on the *Sample* have been completed, then the additional analyses cannot be conducted until consent from the *Athlete* or approval from a hearing body is obtained;

b) If the Laboratory receives a request to conduct Confirmation Procedures for an atypical or suspicious steroid profile of a *Sample*, which are triggered by *ADAMS* notifications after the "A" *Sample* has already been reported as an *Adverse Analytical Finding*, then the Laboratory shall advise the *Testing* Authority or *Results Management* Authority (if different) that if the *Athlete* is charged with a *Code* Article 2.1 anti-doping rule violation, the additional Confirmation Procedures cannot be performed until consent from the *Athlete* or approval from a hearing body is obtained.

- Reporting Times

Reporting of "A" *Sample* results should occur in *ADAMS* within twenty (20)

days of receipt of the *Sample*. The reporting time required for specific occasions (*e.g.* for Major *Events*, see Annex B) may be substantially less than twenty (20) days. 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" *Sample* results.

The Laboratory Documentation Packages and/or Certificates 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) days of the request, unless a different deadline is agreed upon with the *Results Management* Authority or *WADA*, respectively.

- Reporting Requirements

  The Laboratory shall record the test result for each individual *Sample* from *Signatories* or *WADA* in *ADAMS.*

  [Comment: Test results for samples from non-Signatories, except WADA, shall not be reported in ADAMS].

  When reporting test results in *ADAMS*, the Laboratory shall include, in addition to the mandatory information stipulated in *ADAMS*, in the relevant *Technical Document(s),* Technical Letter(s) or Laboratory Guidelines, and in the ISO/IEC 17025 standard, the following:

  - The SG of the *Sample* (Initial *Testing* Procedure and "A" and "B" Confirmation Procedures);
  - The name of the *Results Management* Authority, if provided;
  - 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*);

    [Comment: 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. An opinion or interpretation may include, but not be limited to, recommendations on how to use results, information related to the pharmacology, metabolism and pharmacokinetics of a substance, whether the observed results may suggest the need for additional investigations regarding potential environmental contamination causes and/or Further Analysis and whether an observed result is consistent with a set of reported conditions.]

  - Specific tests performed, in addition to the Laboratory routine Analytical *Testing* menu (*e.g.* EPO GC/C/IRMS, hGH, blood transfusions, DNA, genomic profiling, etc.);
  - Any irregularities noted on *Samples*;

- Any refusal by the *Athlete* and/or his/her representative(s) or the Independent Witness, as applicable, to sign the Laboratory documentation for the "B" *Sample* opening, aliquoting or re-sealing procedures (see Article 5.3.6.2.3).

The Laboratory is not required to provide any additional Test Report, either in hard-copy or digital format, other than the submission of test results in *ADAMS*. All *Anti-Doping Organizations* shall access the Test Reports of their *Samples* in *ADAMS*. Upon request by *WADA*, the Laboratory shall report a summary of the results of analyses performed in a format specified by *WADA*. In addition, the Laboratory shall also provide any information requested by *WADA* in relation to the Monitoring Program (*Code* Article 4.5).

The Laboratory shall qualify the result(s) of the analysis in the *ADAMS* Test Report as:

a) *Adverse Analytical Finding*; or

b) *Atypical Finding*; or

c) Negative Finding; or

[Comment: In cases when the Testing Authority confirms to the Laboratory the existence of an approved TUE for the Prohibited Substance, which is consistent with the Presumptive Adverse Analytical Finding results obtained in the Initial Testing Procedure (see Art 5.3.6.2.2), the Laboratory shall report the result as a Negative Finding as instructed by the Testing Authority.]

d) Not Analyzed

[Comment: Any Sample received at the Laboratory and not subject to Analytical Testing for a valid, documented reason (as instructed by or agreed with the Testing Authority) such as Sample irregularities, intermediate Samples of a Sample Collection Session, etc. (see Article 5.3.3).]

- Test Report for Non-Threshold Substances

a) "A" *Sample* Test Report

The Laboratory is not required to report concentrations for Non-Threshold Substances. The Laboratory shall report the actual *Prohibited Substance(s)* and/or its *Metabolite(s),* or *Marker(s)* of the *Use* of *Prohibited Substance(s)* or *Prohibited Method(s)* present (*i.e.* identified, as per the TD IDCR) in the *Sample* and in accordance with the reporting requirements established in the TD MRPL.

[Comment: 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.]

However, the Laboratory should provide estimated concentrations when possible and for information purposes only, upon request 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* that the concentration was obtained by an Analytical *Testing* Procedure, which has not been validated for quantitative purposes.

b) "B" *Sample* Test Report

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

- Test Report for Threshold Substances

a) "A" *Sample* Test Report

For Threshold Substances, the Laboratory Test Report for the "A" *Sample* shall establish that the identified *Prohibited Substance(s)* or its *Metabolite(s)* or *Marker(s)* is present at a concentration and/or ratio and/or score of measured analytical values greater than the *Decision Limit*, 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 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) "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 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).

5.3.9 Control of Nonconformities in Analytical *Testing*

The Laboratory shall have policies and procedures that shall be implemented when any aspect of its Analytical *Testing* does not comply with set requirements.

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

- 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 and record a thorough Root Cause Analysis of the nonconformity.

- Improvement

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

5.3.10 Complaints

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

5.3.11 Storage of *Samples* [18]

5.3.11.1 Storage of Urine *Samples*

All urine S*amples* 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.*

a) Urine *Sample(s)* without an *Adverse Analytical Finding* or *Atypical Finding*: The Laboratory shall retain the "A" and "B" urine *Sample(s)* without an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of three (3) months after reporting the final analytical result 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, in writing, by the relevant *Testing* Authority or *WADA* [19].

b) Urine *Samples* with Irregularities: The Laboratory shall retain the "A" and "B" urine *Sample(s)* with irregularities for a minimum of three (3) months after reporting in *ADAMS*, or for a longer period as determined by the *Testing* Authority, *Results Management* Authority or *WADA* [19].

c) Urine *Sample(s)* with an *Adverse Analytical Finding* or *Atypical Finding*: The Laboratory shall retain the "A" and "B" urine *Sample(s)* with an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of six (6) months after reporting the final analytical result (for the "A" or the "B" *Sample*, as applicable) in *ADAMS* [20, 21], or for a longer period as informed to the

[18] 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. However, minimum and maximum retention times apply to any Aliquot(s) of a *Sample* that remains after completion of the Analytical *Testing*.

[19] 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. However, the Laboratory may store *Samples* beyond the applicable minimum storage times at their own discretion and expense. In such cases, the Laboratory shall inform the responsible *Testing* Authority. Any Further Analysis on these *Samples* will require the approval of the *Testing* Authority or *WADA*.

[20] If the "B" *Sample* Confirmation Procedure is not performed, the Laboratory may dispose of both the "A" and "B" *Samples* 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 or plasma/serum *Sample(s)* for a minimum of six (6) months after reporting the "B" *Sample* analytical result.

[21] Nevertheless, the Laboratory shall contact and inform the relevant *Testing* Authority and *WADA* before disposing of any *Samples* with *Adverse Analytical Findings* for which the *Testing* Authority or *Results Management* Authority

Laboratory, in writing, by the relevant *Testing* Authority, *Results Management* Authority or *WADA* [19].

d) 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 this Article 5.3.11.1) 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 [19].

5.3.11.2 Storage of Blood *Samples*

A. *Sample*s for which Analytical *Testing* has been performed on blood serum/plasma fraction only (not on cellular components):

All serum or plasma S*amples* retained for storage in the Laboratory shall be stored frozen according to established protocols in a secure location under continuous chain of custody. The Laboratory shall keep all chain of custody and other records (either as hard-copy or in digital format) pertaining to those *Samples*.

a) 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 *WADA* [19].

b) 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 *WADA* [19].

c) 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)

(if different) has not provided instructions about the performance or not of the "B" Confirmation Procedure (see Article 5.3.6.2.3).

in *ADAMS* [20, 21] or for a longer period as informed to the Laboratory, in writing, by the relevant *Testing* Authority, *Results Management* Authority or *WADA* [19].

d) 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 this Article 5.3.11.2) 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 applicable [19].

B. *Samples* for which Analytical *Testing* has been performed on cellular fractions of whole blood.

a) Whole blood "A" and "B" *Samples* without an *Adverse Analytical Finding* or *Atypical Finding*: The Laboratory shall retain the whole blood *Samples* without an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of one (1) month after reporting the final analytical result in *ADAMS* [19].

b) Whole blood *Samples* with irregularities: The Laboratory shall retain the whole blood *Samples* with irregularities for a minimum of one (1) month after reporting the final analytical result in *ADAMS*, or for a longer period as determined by the *Testing* Authority, *Results Management* Authority or *WADA* [19].

c) Whole blood "A" and "B" *Sample(s)* with an *Adverse Analytical Finding* or *Atypical Finding*: The Laboratory shall retain "A" and "B" whole blood *Sample(s)* with an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of three (3) months after reporting the final analytical result (for the "A" or the "B" *Sample*, as applicable) in *ADAMS* [21, 22] or for a longer period as informed to the Laboratory, in writing, by the relevant *Testing* Authority, *Results Management* Authority or *WADA* [19].

d) Whole blood "A" and "B" *Sample(s)* under challenge, dispute or investigation: If the Laboratory has been informed by the *Testing*

[22] If the "B" *Sample* Confirmation Procedure is not performed, the Laboratory may dispose of both the "A" and "B" whole blood *Samples* three (3) months after reporting the "A*" Sample* analytical result. However, if the "B" *Sample* Confirmation Procedure is performed, then the Laboratory shall retain both the "A" and "B" whole blood *Sample(s)* for a minimum of three (3) months after reporting the "B" *Sample* analytical result.

Authority, the *Results Management* Authority or *WADA* (in writing and within the applicable storage period as defined in this Article 5.3.11.2) that the analysis of a whole blood *Sample* is challenged, disputed or under investigation, the Laboratory shall retain both the "A" and "B" *Samples* until further notice by the *Testing* Authority, the *Results Management* Authority or *WADA*, as applicable [19].

5.3.11.3 Long-term Storage of *Samples*

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 for the purpose of Further Analysis, subject to the conditions set out in Articles 5.3.6.3, 5.3.11.1 and 5.3.11.2.

Sample(s) may be stored in long-term storage under the custody of either a Laboratory or another Fit-for-Purpose facility under the responsibility of the *Testing* Authority, which has ownership of the *Sample(s)* pursuant to Article 10.1 of the ISTI. The *Testing* Authority shall retain the *Sample* collection records pertaining to all stored *Samples* for the duration of *Sample* storage.

- Laboratories as *Sample* Custodians

  The Laboratory shall ensure that *Samples* are stored according to established protocols in a secure location in the Laboratory's permanent controlled zone and under continuous chain of custody. The written request from the *Testing* Authority or *WADA* for long-term storage of *Samples* shall be properly documented.

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

  If *Sample(s)* are to be transported for storage at a location outside the secured area of the Laboratory that first analyzed the *Sample(s),* the Laboratory shall secure the "A" *Sample(s)* to be shipped either by re-sealing individual "A" *Sample* container(s) with a tamper-evident sealing system, which has similar capabilities for security and integrity as the original sealing system, or by sealing the box in which the *Sample(s)* are shipped in a manner that maintains *Sample* integrity and chain of custody. Neither the *Athlete* nor his or her representative nor

an Independent Witness is required to be present for this procedure.

[Comment: For example, Sample(s) may be resealed with new resealing systems (e.g. new bottlecaps) produced by the manufacturer of an appropriate Sample collection equipment that replicates the security and tamper-evident functionality of the original seal. The resealing system of shipped "A" Sample(s) shall be tamper evident.]

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

During transport and long-term storage, *Sample(s)* shall be stored at a temperature appropriate to maintain the integrity of the *Sample(s).* In any anti-doping rule violation case, the issue of the *Sample*'s transportation or storage temperature shall be considered where failure to maintain an appropriate temperature could have caused the *Adverse Analytical Finding* or other result upon which the anti-doping rule violation is based.

The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to a stored *Sample* for the duration of *Sample* storage, either as hard-copy or in digital format. In addition, the Laboratory may retain *Sample* analytical data which would allow retrospective analysis of such data, for example, for the purpose of identifying signals for novel *Metabolite(s)* of *Prohibited Substance(s)* or *Marker(s)* of *Prohibited Substance(s)* or *Prohibited Method(s)* (*e.g.* full-scan mass spectrometry data) as detailed in Article 5.3.6.3.

If *Sample(s)* are transported to another Laboratory for long-term storage, the *Sample*'s external chain of custody and other non-analytical records (*e.g.* 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.

- *Testing* Authorities as *Sample* Custodians

  Sample(s) may also be transported for long-term storage to a Fit-for-Purpose, secure *Sample* storage facility, which is under the responsibility of the *Testing* Authority that has ownership over the *Samples*. In such cases, the external storage facility shall have its own ISO accreditation or certification (*e.g.* 17025, 20387, 9001) and shall

maintain security requirements comparable to those applicable to a Laboratory. The *Testing* Authority 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 for the transfer of the *Sample(s)* to long-term storage shall be properly documented. The transfer of the *Samples* to the external long-term storage facility shall also be recorded. The Laboratory shall secure the *Sample(s)* for transportation to the long-term storage facility as described above.

The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to all *Samples* transferred for long-term storage for the duration of *Sample* storage, either as hard-copy or in digital format. In addition, the Laboratory may retain *Sample* analytical data which would allow retrospective analysis of such data. The Laboratory shall transfer the *Sample*'s external chain of custody and other non-analytical records to the *Testing* Authority, either as originals or copies, immediately or upon request.

5.3.12 Secondary Use or Disposal of *Samples* and Aliquots

The Laboratory shall maintain SOP(s) pertaining to the secondary use of *Samples* or Aliquots for research or quality assurance, as well as for the disposal of *Samples* and Aliquots. The requirements of this Article 5.3.12 apply *mutatis mutandis* to an *Anti-Doping Organization* that takes custody of *Samples* for long-term storage.

When the minimum applicable *Sample* storage period has expired (see Articles 5.3.11.1 and 5.3.11.2), 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, or if the Laboratory has not made its own decision to keep the *Samples* for long-term storage, the Laboratory shall do one of the following with the *Sample(s)* and Aliquots as soon as practicable:

5.3.12.1 Disposal of the *Sample(s)* and Aliquots

Disposal of *Samples* and Aliquots shall be recorded under the Laboratory Internal Chain of Custody.

5.3.12.2 Secondary use of *Samples* and Aliquots for Research and Quality Assurance

Samples and Aliquots shall be anonymized to ensure that any subsequent results cannot be traced back to a particular *Athlete* (see *Code* Article 6.3). Only after anonymization, may a *Sample* or Aliquot be used for:

a) Anti-doping research, if the *Athlete* consented to the use of his or her *Sample* for research; or

[Comment: Athlete consent for research, as declared in the DCF or as obtained by other means, shall be recorded in the Laboratory's documentation for reference.]

b) Quality assurance, quality improvement of existing Test Methods, development or evaluation of Analytical *Testing* Procedures for *Prohibited Substances* or *Prohibited Methods* included in the *Prohibited List* at the time of *Sample* collection, or to establish reference population ranges or Thresholds or other statistical purposes. *Athlete*'s consent is not required for these purposes.

The use of *Samples* and Aliquots for the purposes of this Article 5.3.12.2 is subject to the following conditions:

a) The Laboratory must respect *Code* Article 19 and the ISL Code of Ethics requirements related to research, types of permitted research, and respect of ethical standards for research or quality assurance studies involving human subjects;

b) The Laboratory must not make any attempt to re-identify an *Athlete* from *Samples* or Aliquots used for the purposes of this Article 5.3.12.2 or data arising from any research or quality assurance analysis;

c) The Laboratory must consult the applicable national regulations, guidance, or authorities to determine whether a study should be considered as falling under 5.3.12.2 a) or 5.3.12.2 b);

[Comment: If the Laboratory is unsure whether a study can proceed without Athlete consent after consulting the foregoing sources, the Laboratory shall consult with WADA].

d) In the event the Laboratory wishes to transfer *Sample(s)* or Aliquots to be used for the purposes of this Article 5.3.12.2 to another Laboratory or a third-party research institution or group, or wishes to partner with another Laboratory or research institution or group for the purpose of an Article 5.3.12.2 study, the Laboratory shall subject the receiving party to the conditions described in this Article 5.3.12.2 by way of a written agreement and shall prohibit the receiving party from further transferring any *Sample(s)* or Aliquots or related data to another party.

5.4 Management Requirements

5.4.1 Organization

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

5.4.2 Management Reviews

Management reviews will be conducted to meet the requirements of ISO/IEC 17025.

5.4.3 Document Control

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

The Laboratory shall implement a procedure in its Management System to ensure that the contents of ISL, *Technical Documents*, Technical Letters and Laboratory Guidelines are incorporated into the Laboratory's SOPs by the applicable effective date and that implementation is completed, recorded and assessed for compliance. If this is not possible, the Laboratory shall 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.

5.4.4 Control and Storage of Technical Records

The Laboratory shall keep a copy of all *Sample* records to the extent needed to produce Laboratory Documentation Packages or Certificates of Analysis, in accordance with the TD LDOC, in a secure storage until *Sample* disposal or anonymization (see Article 5.3.12).

In addition, this information shall be stored for ten (10) years from collection date for all *Sample* data and chain-of-custody information related to the *Athlete Biological Passport (e.g.* hematological and steroid profile *Markers*)

5.4.5 Cooperation with Customers and with *WADA*

Cooperation with customers shall be handled in accordance with ISO/IEC 17025.

- Ensuring 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* of new substances;
- Provide documentation to *WADA* [*e.g.* Management System documentation, SOPs, contracts (not including commercial or financial information) with *Signatories*, or with *Sample* Collection Authorities or *Delegated Third Parties* working on behalf of *Signatories*] upon request to ensure conformity with the rules established under the *Code* as part of the maintenance of *WADA* accreditation. This information shall be treated in a confidential manner.

- Ensuring 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 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 *Results Management* Authority concerning any significant question of Analytical *Testing* needs or any unusual circumstance in the Analytical *Testing* process (including delays in reporting);
  - Providing complete, timely and unbiased explanations to the *Testing* Authority and/or *Results 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. The requests from such expert testimonies shall originate, in writing, from the *Testing* Authority, *Results Management* Authority, *WADA* or hearing bodies as part of the *Results Management* process. The Laboratory shall not provide expert testimony to *Athletes* or *Athletes*' representatives, including their legal counsels;
  - Responding to any complaint submitted by a *Testing* Authority or *Results Management* Authority concerning the Laboratory and its operation.

As required by ISO/IEC 17025, the Laboratory shall actively monitor the quality of the services provided to the relevant *Anti-Doping 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's Management System where appropriate.

6.0 *WADA* External Quality Assessment Scheme (EQAS)

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 their proficiency, and to improve test result uniformity between Laboratories. EQAS samples are used to assess Laboratory routine analytical capacity and performance, reporting turn-around times and overall compliance with *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 its educational components, a source of continuous improvement for the effectiveness of the Analytical *Testing* Procedures.

6.1 Types of EQAS

6.1.1 Blind EQAS

The Laboratory will be aware that the sample is an EQAS sample 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 that the sample is an EQAS sample since it is delivered by a *Testing* Authority and is indistinguishable from routine *Samples*.

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 Article 4.4.2.2) before the subsequent application of the Analytical *Testing* Procedure to the routine analysis of *Samples*.

6.2 EQAS Sample Number and Composition

6.2.1 Number of EQAS Samples

The actual composition and number of EQAS samples supplied to different Laboratories may vary; however, within any calendar year, all Laboratories

participating in the EQAS are expected to have analyzed the minimum total number of EQAS samples.

Each year, the EQAS program will consist of:

- 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.

As part of *WADA*'s Laboratory monitoring activities, and with the main purpose of assisting Laboratories in their 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 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*) for a specific Analytical *Testing* Procedure, which is not part of the Laboratory's routine Analytical *Testing* menu;
- As part of *WADA* Laboratory assessments.

6.2.2 Composition of EQAS Samples

EQAS samples may or may not contain *Prohibited Substance(s)* and/or *Metabolite(s)* of *Prohibited Substance(s)* and/or *Marker(s)* of *Prohibited Substance(s)* or *Prohibited Method(s).*

6.2.2.1 Blank EQAS Samples

Blank EQAS samples do not contain *Prohibited Substances* or their *Metabolites* or *Markers* of *Prohibited Substances* or *Prohibited Methods.*

6.2.2.2 Adulterated EQAS Samples

Adulterated EQAS samples are those which have been deliberately adulterated by the spiking of non-characteristic *Metabolite(s)* or by the addition of extraneous substances designed to dilute or concentrate the sample, degrade or mask the Analyte prior to or during the analytical determination. Adulterated EQAS samples may also be obtained from the controlled administration or the addition of non-prohibited substances, which share common *Metabolite(s)* with *Prohibited Substance(s).*

6.2.2.3 EQAS Samples Containing *Prohibited Substance(s)*, their *Metabolite(s)* or *Marker(s)*, or the *Marker(s)* of *Prohibited Method(s)*

The concentration(s) of selected Analyte(s) are those that may be encountered in the urine or blood after *Use* of *Prohibited Substance(s)* or *Prohibited Method(s).* For some Analytes, the EQAS sample may contain the parent *Prohibited Substance* and/or its *Metabolite(s)* and/or its *Marker(s).*

EQAS samples may be spiked with *Prohibited Substance(s)* and/or their *Metabolite(s)* or *Marker(s)* but would be preferably prepared from controlled administration studies. The EQAS sample composition shall reflect as closely as possible the expected target Analyte *Metabolite* pattern and concentrations usually found in *Samples*.

An EQAS sample may contain more than one *Prohibited Substance*, *Metabolite(s),* or *Marker(s)* of a *Prohibited Substance or Prohibited Method*. It may also contain multiple *Metabolites* or *Markers* of a single *Prohibited Substance* or *Markers* of a *Prohibited Method*, which would represent the presence of a single *Prohibited Substance* or the *Use* of a single *Prohibited Method*.

[Comment: Double-blind EQAS samples should be representative of Samples. Therefore, to the extent possible (in consideration, for example, of technical or ethical constraints, availability of the pharmaceutical grade substance, etc.), double-blind EQAS samples containing Prohibited Substance(s) and/or Metabolite(s) of Prohibited Substance(s) and/or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) should be prepared from controlled administration studies performed in human subjects. However, if this is not possible, then the double-blind EQAS sample(s) may be prepared by spiking expected target Analyte(s) in the Sample matrix in consideration of the representative metabolic profile(s).]

- EQAS samples for Non-Threshold Substances

  For Non-Threshold Substances, the concentration in the EQAS sample will be guided by, but not limited to, one of the following criteria:

  - Concentrations of the *Prohibited Substance* and/or its *Metabolite(s)* or *Marker(s)* equal to or greater than (≥) the applicable MRPL (refer to TD MRPL);
  - Concentrations of the *Prohibited Substance* and/or its *Metabolite(s)* or *Marker(s)* between 50% of the MPRL and the MRPL (applicable only to Non-Threshold Substances prohibited at all times and with no *Minimum Reporting Levels*, as per TD MRPL);
  - Non-Threshold Substances with *Minimum Reporting Levels* 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 *Minimum Reporting Level*;

- Concentrations of the *Prohibited Substance* and/or its *Metabolite(s)* or *Marker(s)* below (<) 50% of the applicable MRPL (for Non-Threshold Substances prohibited at all times with no *Minimum Reporting Levels*, for educational purposes).

- EQAS samples for Threshold Substances

  For Threshold Substances, the concentration in the EQAS sample will be guided by, but not limited to, one of the following criteria:

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

Laboratories shall determine the *Markers* of the "steroid profile" in all urine EQAS samples (unless specifically noted as not required in an educational EQAS sample).

6.2.2.4 Blood EQAS Samples for the analysis of *ABP* blood *Markers*

These EQAS samples are distributed to Laboratories and *ABP* Laboratories 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*.

6.2.3 Laboratory Analytical *Testing* Procedures Used in EQAS

All procedures associated with the Analytical *Testing* of the EQAS samples by the Laboratory are to be conducted in a manner similar to that applied to routine *Samples*, unless otherwise specified by *WADA*. No effort shall be made to optimize instrument (*e.g.* change multipliers or chromatographic columns) or method performance prior to analyzing the EQAS samples unless it is a scheduled maintenance activity. Only validated, Fit-for-Purpose Analytical *Testing* Procedures described in the Laboratory's SOPs are to be employed in the analysis of EQAS samples (*i.e.* using the Initial *Testing* Procedures and Confirmation Procedures applied in routine Analytical *Testing*).

6.3 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 valid 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).

6.3.1 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 Article 5.3.8.4) 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 reporting date unless an extension is granted by *WADA* for valid reasons. For a failure to report results of blind EQAS samples by the established deadline, without prior approval by *WADA* or without justified grounds, as determined by *WADA*, the Laboratory shall receive two (2) penalty points, and an additional two (2) penalty points for reporting eight (8) to fourteen (14) days beyond the applicable deadline (refer to the Points Scale Table in Article 7.3). Failure to report blind EQAS results within fifteen (15) days beyond the *WADA*-established or *WADA*-approved deadline (based on valid justification, as determined by *WADA*) will result in the evaluation of the corresponding EQAS sample(s) as False Negative Finding(s) (for those findings produced by different and unrelated root causes) and the assignment of penalty points in accordance with the Points Scale Table in Article 7.3. In such cases, no penalty points will be accumulated for late reporting, in addition to those assigned for the False Negative Finding(s).

6.3.2 Reporting Double-Blind EQAS Results

The Laboratory shall report the results of double-blind EQAS samples in *ADAMS* as per Article 5.3.8.4.

Reporting of double-blind EQAS results should occur within twenty (20) 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 or a postponement has been established or approved by

WADA based on justified grounds (*e.g.* double-blind EQAS samples for which a second opinion may be required before reporting an *Adverse Analytical Finding*).

Failure to report double-blind EQAS results within twenty (20) days of receipt of the samples or, subject to an extension of this deadline by agreement with the *Testing* Authority or approval by *WADA* based on justified grounds, within the agreed or *WADA*-approved deadline, shall carry two (2) penalty points and an additional two (2) penalty points for reporting eight (8) to fourteen (14) days beyond the applicable deadline (refer to the Points Scale Table in Article 7.3). Failure to report double-blind EQAS results within thirty-five (35) days of receipt of the samples, or otherwise within fifteen (15) days beyond the agreed or *WADA*-approved deadline, will result in the evaluation of the corresponding EQAS sample(s) as False Negative Finding(s) (for those findings produced by different and unrelated root causes) and the assignment of penalty points in accordance with the Points Scale Table in Article 7.3. In such cases, no penalty points will be accumulated for late reporting, in addition to those assigned for the False Negative Finding(s).

6.3.3 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.

6.3.4 Reporting Results for EQAS Samples Containing Non-Threshold Substances

Unless otherwise specified by *WADA* (for example, for an educational EQAS), the report of EQAS results for Non-Threshold Substances shall include all the Analytes whose presence in the EQAS sample has been confirmed by the Laboratory in accordance with the TD IDCR or other applicable *Technical Document*, 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).

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.

6.3.5 Reporting Results for EQAS Samples Containing Threshold Substances

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.

[Comment: Unless otherwise specified by WADA (for example, for educational purposes), this provision does not apply to EQAS samples containing exogenous Threshold Substances whose presence shall be reported, without the need for quantitative confirmation, if detected in the presence of diuretics or masking agents.]

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 Points Scale Table in Article 7.3 below) has been developed by the 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 and over a consecutive twelve (12)-month period [23] is necessary for maintaining *WADA* accreditation.

[Comment: An EQAS Round is a distribution of EQAS sample(s) to the Laboratories and the probationary laboratories for Analytical Testing as defined by WADA.]

Unsatisfactory performance in an educational EQAS for a new or *WADA*-specific Analytical *Testing* Procedure may prevent the Laboratory from seeking an extension of the Laboratory's Scope of ISO/IEC 17025 Accreditation for the Analytical *Testing* Procedure and from its application in routine Analytical *Testing* (see Article 4.4.2.2). In such circumstances, 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.

[Comment: 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, method 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 Article 4.4.2.2).]

[23] The twelve (12)-month period to account for the total number of penalty points accumulated by a Laboratory or probationary laboratory according to the Points Scale Table is defined as the most recent consecutive twelve (12)-month interval starting either from the date that the Laboratory or the probationary laboratory reported the nonconforming result (EQAS or routine Analytical *Testing*, as applicable) 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 twelve (12)-month period; however, the total number of penalty points within any consecutive twelve (12)-month period shall not reach the maximum allowed number of penalty points established in the Points Scale Table.

7.1.1 EQAS Samples Containing Non-Threshold Substances

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.

The results for any Non-Threshold Substance and/or its *Metabolite(s)* and/or *Marker(s)* at concentrations greater than (>) the MRPL (or exceeding 120% of the *Minimum Reporting Level*, when applicable) shall be evaluated in accordance with the Points Scale Table.

The results for any Non-Threshold Substance and/or its *Metabolite(s)* and/or *Marker(s)* at concentrations between 50% of the MRPL and the MRPL (or less than 120% of the *Minimum Reporting Level*, when applicable) 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.

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

For EQAS samples containing Threshold Substances at levels greater than (>) 50% of the Threshold, the quantitative determination will be statistically evaluated (*e.g. z*-score, degree of equivalence analysis) to determine the compatibility of the reported result with the assigned value (reference, nominal or consensus value, as applicable). Results shall be evaluated as per the Points Scale Table.

[Comment: 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.]

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.

[Comment: 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 one (1) decimal place) for the Laboratory's quantitative result is < 3.0 (see footnote 31).]

7.1.2.1 Unsatisfactory Quantitative Result for Threshold Substances (absolute *z*-score ≥ 3.0) [24]

The Laboratory shall provide *WADA* with a satisfactory Corrective Action Report for an unsatisfactory quantitative result. The Corrective Action Report shall be submitted within fifteen (15) 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 Points Scale Table.

[Comment: 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.]

7.1.2.2 Questionable Quantitative Result (absolute *z*-score > 2.0 and < 3.0)

The Laboratory shall perform an internal investigation to determine the root cause(s) of the questionable result and implement appropriate corrective measures to resolve them.

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

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

Where:

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

7.2 Evaluation of Laboratory Performance

7.2.1 False *Adverse Analytical Finding*

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.

7.2.1.1 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 seven (7) days of informing *WADA* or being informed by *WADA*, as applicable, or, in exceptional cases, as otherwise agreed with *WADA*.

The LabEG shall review the Laboratory's Corrective Action Report within seven (7) days, or within a timeline otherwise determined by *WADA*, and establish the source of the incorrect result as either a technical/methodological error or a clerical/administrative error.

The Laboratory may be required by *WADA* to analyze additional EQAS samples and/or to review the relevant analytical results and to re-analyze any relevant and available *Samples* previously reported as *Adverse Analytical Findings* [25] during the preceding twelve (12) months (or during a period

[25] The Laboratory may not re-analyze *Sample*(*s)* previously reported as *Adverse Analytical Findings* if the responsible *Anti-Doping Organization* has charged the *Athlete* with a *Code* Article 2.1 anti-doping rule violation resulting from the analysis of the *Sample*, without the consent of the *Athlete* or approval from a hearing body. However, in connection with its monitoring of a Laboratory, *WADA* may direct Further Analysis of a *Sample* which has resulted in an Article 2.1 anti-doping rule violation charge without consent of the *Athlete* or approval from a hearing body as provided in *Code* Article 6.5, provided that the analytical result from this analysis may not be used against the *Athlete* [for example, re-analyzing *Samples* which a Laboratory has reported as *Adverse Analytical*

otherwise determined by *WADA*) within seven (7) 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.

[Comment: The retrospective review of the analytical results and re-analysis of previous relevant Samples reported as Adverse Analytical Finding(s) shall be performed with the objective of determining whether any other related [i.e. produced by the same root cause(s)] False Adverse Analytical Finding(s) have been reported by the Laboratory. The discovery of additional false Adverse Analytical Finding(s) shall lead to the implementation of corrective measures and shall be communicated to the responsible Testing Authority/Results Management Authority and to WADA. However, the additional False Adverse Analytical Finding(s) will not lead to the accumulation of additional penalty points if produced by the same root cause(s), as determined by WADA.]

a) False *Adverse Analytical Finding* with *Consequences* being imposed on an *Athlete*

If the reporting of the False *Adverse Analytical Finding* has resulted in *Consequences* being imposed against an *Athlete*, the Laboratory shall receive twenty (20) penalty points in accordance with the Points Scale Table, irrespective of the nature of the error (technical/methodological or clerical/administrative) that led to the reporting of the False *Adverse Analytical Finding*.

[Comment: WADA shall inform a Laboratory in writing about the imposition of penalty points, as decided by the LabEG and in accordance with the 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) that have been 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).]

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

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Findings when other *Sample(s)* analyzed by the Laboratory using the same Analytical Method have been discovered to be False *Adverse Analytical Finding(s)*].

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.

[Comment: During the period of Suspension, the Laboratory shall follow the instructions provided in Article 4.6.5.2 in regard to Samples in the Laboratory's possession at the time of Suspension. Alternatively, if an Analytical Testing Restriction has been imposed, the Laboratory shall subcontract the affected analyses as provided in Articles 4.6.5.1 and 5.2.6.

During the Suspension or Analytical Testing Restriction period, WADA will conduct an assessment (preferably on-site) of the Laboratory, 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.]

b) 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 identifies the error as technical or methodological, the Laboratory will be initially imposed twenty (20) penalty points in accordance with the 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 twenty (20) penalty points initially assigned.

  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 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*. The Laboratory will be able to resume Analytical *Testing* activities following written notification by *WADA*, provided that the point total accumulated by the Laboratory for a twelve (12)-month [23] period does not exceed thirty (30) points.

  However, 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 seven (7) 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.

- Clerical/Administrative Error [26]

  If the Root Cause Analysis investigation performed by the Laboratory identifies the error as clerical or administrative, the Laboratory will be initially assigned fifteen (15) penalty points in accordance with the 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 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 Points Scale Table. The Laboratory will be informed by *WADA*, in writing, of the total amount of penalty points assigned in connection with the reporting of the False *Adverse Analytical Finding*. The Laboratory will be able to resume Analytical *Testing* activities following written notification by *WADA*, provided that the point total accumulated by the Laboratory for a twelve (12)-month [23] period does not exceed thirty (30) points.

  However, if the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and grant an opportunity to resubmit a revised Corrective Action Report within seven (7) days (or as otherwise agreed with *WADA*). If the Laboratory is unable to submit 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 Points Scale Table. The LabEG,

[26] For the purposes of Laboratory performance evaluation, clerical/administrative errors are defined as those incidental, non-systematic errors of no technical or methodological origin, which have been committed by the Laboratory during the performance of Analytical *Testing* (*e.g.* a typographical error when manually recording an analytical result). The Laboratory shall bear no responsibility for clerical/administrative errors reflected in the Laboratory documentation, which were made, for example, by the *Sample* Collection Authority or *Testing* Authority.

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.

7.2.1.2 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 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 fifteen (15) days of being informed by *WADA* (unless otherwise indicated by *WADA*). In addition, the Laboratory may be 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* [25] during the preceding twelve (12) months (or during a period otherwise determined by *WADA*), within seven (7) 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*. The re-analysis shall be documented, and the results shall be reported to *WADA*. The Laboratory will be required to inform all of its clients whose Analytical *Testing* results may have been affected.

The LabEG shall review the Laboratory's Corrective Action Report within fifteen (15) 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 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 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 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.

  However, 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 submit a revised Corrective Action Report within seven (7) 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.

- Clerical/Administrative Error [26]

  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 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 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 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*.

However, 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 seven (7) days (or as otherwise agreed with *WADA*). If the Laboratory is unable to submit 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 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.

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 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 or double-blind EQAS sample or during routine Analytical *Testing* shall be informed of the False Negative Finding as soon as possible by *WADA*.

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 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 fifteen (15) days (unless otherwise indicated by *WADA*).

The LabEG shall review the Laboratory's Corrective Action Report within fifteen (15) days, or within a timeline otherwise determined by *WADA*.

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 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.

However, 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 seven (7) 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 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 additional 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 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.

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 assessment and the requirement that the Laboratory analyses additional EQAS samples.

7.2.3 Further Procedural Evaluations [27]

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 *WADA* Laboratory 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) 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 seven (7) 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.

7.3 Overall Laboratory 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 nonconformities or failures to perform as indicated in the 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 Points Scale Table below, shall prompt the LabEG to make a recommendation to the Chair of the *WADA* Executive Committee to impose

[27] 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 Arts. 7.2.1 and 7.2.2, respectively.

an Analytical *Testing* Restriction against the Laboratory or to impose a Suspension of the Laboratory's *WADA* accreditation, as applicable.

When a Laboratory's *WADA* accreditation is suspended:

- If a Laboratory under Suspension accumulates the maximum allowed number of penalty points in the EQAS, as determined in the Points Scale Table below, and the Laboratory is not capable of correcting the issue(s) before the end of the Suspension period, then the LabEG shall make a recommendation to the Chair of the *WADA* Executive Committee to extend the Laboratory's Suspension for up to an additional six (6) months or until such a time when the Laboratory can satisfactorily correct all the issues identified;
- If the Laboratory under Suspension accumulates the maximum allowed number of penalty points during an extended period of Suspension (beyond the initial six (6) months), then the LabEG may recommend the Revocation of the Laboratory's accreditation to the *WADA* Executive Committee;
- Any accrued penalty points leading up to the Suspension or further accumulated through the Laboratory's participation in the blind EQAS program during the Suspension period, are reset to zero (0) upon reinstatement of its *WADA* accreditation [28].

When a Laboratory is subject to an Analytical *Testing* Restriction:

- Laboratories under an Analytical *Testing* Restriction remain operational (except for the activity(-ies) under the Analytical *Testing* Restriction) and, therefore, are evaluated during the Analytical *Testing* Restriction as any other, fully operational Laboratory;
- 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 twelve (12)-month period [23]), are carried over after the lifting of the Analytical *Testing* Restriction. Any penalty points accrued in relation to the Analytical *Testing* Restriction are removed after the lifting of the Analytical *Testing* Restriction.

[28] This provision does not apply to a voluntary cessation of Laboratory operations (see Article 4.6.7).

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Points Scale Table for Assessment of Laboratory and Probationary Laboratory Performance

Analytical *Testing* Conditions	**Nonconformity**	**Type of Error** Outcome	**Penalty Points**	**Actions and Sanctions**
Routine Analytical *Testing* (Art 7.2.1.1)	**False *AAF*** **+** ***Consequence* for the *Athlete***	**Technical / Methodological error** or **Clerical / Administrative error**	**20**	**Cease Analytical *Testing*** and **Suspension / Analytical *Testing* Restriction**
Routine Analytical *Testing* (Art 7.2.1.1) Or **EQAS (blind or double blind) round** (Art 7.2.1.2)	**False *AAF*** **+** **No *Consequence* for the *Athlete***	**Technical / Methodological error**	**20**	**Cease Analytical *Testing***
		• Self-reporting [29]	**- 5**	**Resume Analytical *Testing***
		• Satisfactory and timely CAR	**- 10**	
		• Unsatisfactory CAR	**+ 5**	**Suspension / Analytical *Testing* Restriction**
		Clerical / Administrative error	**15**	**Cease Analytical *Testing***
		• Self-reporting [29]	**- 5**	**Resume Analytical *Testing***
		• Satisfactory and timely CAR	**- 10**	
		• Unsatisfactory CAR	**+ 10**	**Suspension / Analytical *Testing* Restriction**
Routine Analytical *Testing* Or **EQAS (blind or double blind) round**	**False Negative Finding** (Art 7.2.2)	**False Negative Finding**	**10**	**Additional EQAS samples** [30]
		• Self-reporting [29]	**- 5**	
		• Satisfactory and timely CAR	**- 5**	
		• Unsatisfactory CAR	**+ 5**	

[29] Voluntary self-reporting is not applicable to blind EQAS samples.

[30] The results of the analysis of the additional EQAS samples will be evaluated in accordance with this Points Scale Table.

EQAS Evaluation	Result		Penalty Points
Steroid Profile *Markers* |*z*-score| ≥ 3.0 (Occurrences*)	**|*z*-score| ≥ 3.0 and CAR**		
	4-7	Unsatisfactory CAR	**2**
		Satisfactory and timely CAR	1
	8-12	Unsatisfactory CAR	**4**
		Satisfactory and timely CAR	2
	13-18	Unsatisfactory CAR	**6**
		Satisfactory and timely CAR	3
	≥ 19	Unsatisfactory CAR	**8**
		Satisfactory and timely CAR	4
GC/C/IRMS $\delta^{13}C$ (≥ 3 Occurrences**) **Threshold Substances** (per occurrence)	**2.0 < |z-score| < 3.0** Internal Investigation		**0**
	|*z*-score| ≥ 3.0 [31] Unsatisfactory CAR		**5**
	|*z*-score| ≥ 3.0 [31] Satisfactory and timely CAR		**0**
SG determination (per occurrence)	**|*z*-score| ≥ 3.0** Unsatisfactory CAR		**1**
Documentation* or Technical Issue** (per occurrence)	**ISL, *TD* or TL Nonconformity**		**2**
	Unsatisfactory CAR		**2**
	Late Submission of CAR (per 7 days beyond the deadline)		**1**
	Late reporting of blind or double-blind EQAS results [32] (late reporting 8 to 14 days beyond the deadline)		**2** **2**

Evaluation	Penalty Points	Sanction
Point Total for single EQAS round (blind or double-blind**)**	**≥ 20**	**Suspension** **Or** **Analytical *Testing* Restriction**
Point Total for double-blind EQAS** for 12-month period** [23]		
Point Total for routine Analytical *Testing* for 12-month period** [23]		
Point Total (blind and double-blind EQAS and routine Analytical *Testing*)** for 12-month period** [23]	**≥ 30**	

***** Based on a total of 6 determinations: Androsterone (A), Etiocholanolone (Etio), Testosterone (T), Epitestosterone (E), 5α-androstane-3α,17β-diol (5αAdiol) and 5β-androstane-3α,17β-diol (5βAdiol) per EQAS sample.

****** Per EQAS sample subjected to GC/C/IRMS analysis.

******* Documentation includes but is not limited to Laboratory Documentation Packages, Corrective Action Reports and Test Reports.

******** Probationary laboratories are exempt from the double-blind EQAS program and routine Analytical *Testing*.

[31] 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 Arts. 7.2.1.2 and 7.2.2, respectively.

[32] See Arts. 6.3.1 and 6.3.2.

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 and at the expense of the probationary laboratory, samples from past EQAS rounds in order to allow the probationary laboratory an opportunity to evaluate its performance against the recorded performance of Laboratories. Composition of the probationary EQAS samples corresponds to the criteria described in Article 6.2.2.

Successful participation in *WADA* probationary EQAS, based on the 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 [23] period) 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 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 each year and will consist of a minimum of fifteen (15) blind samples. At least three (3) blind EQAS samples will contain Threshold Substances. Blank samples may also be included.

7.4.1 Analytical *Testing* Procedures Utilized by Probationary Laboratories for the Analysis of EQAS samples

All procedures associated with the handling and analysis of the EQAS samples by the probationary laboratory are to be conducted using validated procedures in a manner identical to those expected to be applied during routine Analytical *Testing*, unless otherwise specified by *WADA*.

7.4.2 False *Adverse Analytical Finding* Result

Any False *Adverse 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 corrective and preventive action(s) have been implemented, as determined by the LabEG. *WADA* may decide to send a set of EQAS samples and/or perform an assessment of the probationary laboratory prior to its re-instatement to the probationary status.

7.4.3 False Negative Finding

Any probationary laboratory reporting a False Negative Finding in a blind EQAS round shall be informed by *WADA* as soon as possible. The probationary laboratory shall take and report proper corrective and preventive action(s) within ten (10) days of the date of the letter from *WADA* (unless informed otherwise by *WADA*). The corrective

action, if approved by *WADA*, shall be implemented in the routine operations of the probationary laboratory as soon as possible.

7.4.4 Threshold Substance Result

A probationary laboratory shall achieve satisfactory quantitative EQAS results reported based on the mean of three (3) independent determinations.

7.4.5 Overall Probationary Laboratory Evaluation

WADA will evaluate probationary laboratory EQAS performance for each round and assign points for each noncompliance or failure to perform in accordance with the Points Scale Table, with the exception of the double-blind EQAS and routine analysis evaluation.

The Suspension period of a probationary laboratory's participation in the EQAS shall be determined by *WADA.*

Serious and repeated issues in the probationary EQAS shall result in the removal of the laboratory's status as a probationary laboratory by *WADA.*

When the performance of a probationary laboratory is considered to be satisfactory in the EQAS over the most recent and consecutive twelve (12)-month [23] period (*e.g*. at least fifteen (15) blind EQAS samples), and provided that all of other necessary conditions have been fulfilled, *WADA* will provide the probationary laboratory with a minimum of a further fifteen (15) blind EQAS samples to be analyzed as part of a Final Accreditation Test (FAT). In addition, the laboratory will be audited by an assessment team appointed by *WADA*. At *WADA*'s discretion, the FAT and on-site assessment may be conducted separately or at the same time.

The results of the FAT will be evaluated by *WADA* as satisfactory if:

- No False *Adverse Analytical Finding* is reported;
- Less than twenty (20) penalty points are assigned for the EQAS samples tested;
- Any corrective actions required as a result of the *WADA* assessment and/or the analytical performance and/or the presentation of the requested Laboratory Documentation Package(s) shall be submitted within thirty (30) days, unless otherwise specified by *WADA*, and shall be considered 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) days prior to the end of the Suspension period (unless otherwise indicated by *WADA*). Failure to do so will preclude the laboratory from participating in the probationary EQAS.

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 Article 4.2).

PART THREE: ISL ANNEXES

ISL ANNEX A - CODE OF ETHICS FOR LABORATORIES and *ABP* LABORATORIES

1.0 Confidentiality

Directors of Laboratories and *ABP* Laboratories, their delegates and all Laboratory staff shall respect and comply with ISL Article 5.3.8.3 and *Code* Article 14.3.6.

2.0 Research in Support of *Doping Control*

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

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

2.1 Research on Human Subjects

The Laboratories and *ABP* Laboratories shall follow the Helsinki Declaration 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.

Athletes who may undergo *Doping Control Testing* by *Anti-Doping Organizations* shall not be the subjects of drug administration studies that include *Prohibited Substances* or *Prohibited Methods*.

2.2 Controlled Substances

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

3.0 Analysis

The Laboratory or *ABP* Laboratory shall not engage in any analysis or activity that undermines or is detrimental to the World Anti-Doping Program.

[Comment: The World Anti-Doping Program comprises the anti-doping programs of WADA and all 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).]

3.1 Analytical *Testing* for *Anti-Doping Organizations* (*Signatories* or *WADA*)

The Laboratories and *ABP* Laboratories shall accept *Samples* for Analytical *Testing* from *Anti-Doping Organizations* only if all of the following conditions have been met:

- 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 *ABP* Laboratory in accordance with the ISTI; and
- The collection is a part of a legitimate anti-doping program, as determined by *WADA*, or satisfies any of the conditions for *Sample* analysis indicated in ISL Article 5.3.6.

3.2 Analytical *Testing* for non-*Signatories*

Laboratories and *ABP* Laboratories shall not accept *Samples* directly from individual *Athletes* or from individuals or organizations acting on their behalf.

Laboratories or *ABP* Laboratories may accept samples from non-*Signatories* for analysis; however, any such analysis shall not be conducted under the Laboratory's *WADA* accreditation or under the *ABP* Laboratory's *WADA* approval and test results shall not be reported in *ADAMS*. In addition, such analyses shall not negatively affect the Analytical *Testing* of *Samples* from *Anti-Doping Organizations*, concerning, in particular, the allocation of resources (*e.g.* human, financial, instrumental resources) and the reporting of results in a reliable and timely manner.

[Comment: A Laboratory or ABP Laboratory shall only refer to its WADA accreditation or approval status, as applicable, for an activity that falls under its Analytical Testing activities for Anti-Doping Organizations. For the avoidance of doubt, laboratory test reports or other documentation or correspondence related to samples from non-Signatories shall not declare or represent that any such testing is covered under the laboratory's WADA-accredited or -approved status].

3.3 Clinical or Forensic Analysis

Occasionally the Laboratory may be requested to analyze a sample for a banned drug or endogenous substance coming from a hospitalized or ill *Person* in order to assist a physician in the diagnostic process. In such circumstances, the Laboratory Director shall agree to analyze the sample only if the organization making the request provides a letter explaining the medical reason for the test and explicitly certifying that the requested analysis is for medical diagnostic or therapeutic purposes.

The Laboratory may conduct work to aid a forensic and/or legal investigation, but due diligence should be exercised to ensure that the work is requested by an appropriate agency or organization. The Laboratory should not engage in analytical activities or expert testimony that would intentionally question the integrity of an individual or the scientific validity of work performed in the anti-doping program.

3.4 Other Analytical Activities

The Laboratory or *ABP* Laboratory shall not provide analytical services in a *Doping Control* adjudication, unless specifically requested by the responsible *Testing* Authority or *Results*

Management Authority (if different), *WADA* or a hearing body.

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 a hearing body as part of a *Results Management* or adjudication process; or
- If done as part of a legitimate anti-doping research program, as determined by *WADA*; or
- If a request is made by an *Athlete*, the Laboratory may conduct the analysis if agreed by the *Anti-Doping Organization*, which may also specify conditions that must be followed prior to or during the analysis (*e.g.* verification of original sealed packages, product batch number).

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 Articles 3.3 and 3.4 of Annex A will not fall under the *WADA*-accredited or -approved status of the laboratory and shall not negatively affect the Analytical *Testing* of *Samples* from *Anti-Doping Organizations*.

[Comment: For the avoidance of doubt, laboratory test reports or other documentation or correspondence related to these other analytical activities shall not declare or represent that any such testing is covered under the laboratory's WADA-accredited or -approved status.]

3.5 Sharing of Knowledge

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) days. 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.

The Laboratory Director or staff shall participate in developing standards for best practice and enhancing uniformity of Analytical *Testing* in the *WADA*-accredited laboratory system.

[Comment: 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.]

4.0 Duty to Preserve the Integrity of the World Anti-Doping Program and to Avoid any Detrimental Conduct

The personnel of Laboratories and *ABP* Laboratories shall not engage in conduct or activities that undermine or are detrimental to the World Anti-Doping Program. Such conduct could include, but is not limited to, fraud, embezzlement, perjury, etc. that would cast doubt on the integrity of the anti-doping program.

All employees of Laboratories and *ABP* Laboratories 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.

No employee or consultant of Laboratories and *ABP* Laboratories 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*.

No employee or consultant of Laboratories and *ABP* Laboratories shall provide information about a Test Method to an *Athlete* or *Athlete Support Personnel*, which could be used to avoid the detection of doping.

No staff of Laboratories and *ABP* Laboratories shall assist an *Athlete* in avoiding collection of a representative *Sample* (*e.g.* advice on masking strategies or detection windows).

[This does 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 Method*s.]

If a staff member of a Laboratory or *ABP* Laboratory is requested to provide evidence in anti-doping proceedings, they are expected to provide independent, scientifically valid expert testimony.

The Laboratory or *ABP* Laboratory shall not issue any statements related to its analytical processes or findings, unless otherwise provided in *Code* Article 14.3.6. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be the sole responsibility of the responsible *Anti-Doping Organization(s)*.

5.0 Breach and Enforceability

A failure to respect any of the provisions of this Code of Ethics may result in the Laboratory or *ABP* Laboratory 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 Article 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 *ABP* Laboratory being subject to disciplinary action by the Laboratory or *ABP* Laboratory, 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 – ACCREDITATION REQUIREMENTS FOR MAJOR *EVENTS*

The accreditation requirements described herein apply to those Major *Events* which, in order to conduct appropriate *Doping Control*, would require either a significant increase of the existing Laboratory's resources and capacity or the establishment of a temporary "satellite facility" by an existing Laboratory.

Major Event Organizations should give preference to the use of an existing Laboratory for the analysis of *Samples*. However, in some cases, the reporting time requirements for a Major *Event* may require that a Laboratory facility be located in proximity to the Major *Event* such that *Samples* can be delivered by *Doping Control* staff. This may require the creation of a temporary "satellite facility" by an existing Laboratory, which shall have appropriate capabilities for the Major *Event* and be established sufficiently in advance to allow for the timely transfer and validation of Laboratory operations and Test Methods.

In addition, the Laboratory operations necessary for a Major *Event* may be such that the existing Laboratory's analytical and *Sample* handling capacity 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 Director of the Laboratory designated to perform the Analytical *Testing* shall ensure that a proper Management System, performance, security and safety are maintained.

There shall be an agreement, sufficiently ahead of the Major *Event,* between the *Major Event Organization* and the 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 for the Major *Event*. The Laboratory shall be responsible for providing *WADA* with regular and timely progress reports regarding its preparations for the Major *Event.*

1.0 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* is required. However, the Laboratory shall meet the requirements listed below in Annex B Articles 1.1 to 1.4.

All new Test Methods for the Major *Event* shall be validated at least one (1) month prior to start of Analytical *Testing* for the Major *Event*. In addition, any changes to Test Methods, equipment or other procedures in the Management System shall also be validated prior to the start of Analytical *Testing* for the Major *Event.*

1.1 Participation in *WADA* Assessment(s)

WADA may perform one or more assessment(s) (preferably on-site) of the Laboratory's existing facilities with the aim to evaluate the Laboratory operations and capability to provide Analytical *Testing* services for the Major *Event*. The number and type of assessments (on-site, remote and/or documentary audit) will be determined by *WADA* based on the scale of the Major *Event*'s Test Distribution Plan and the Laboratory's progress in preparing for the

Major *Event*. These assessment(s) may include analysis of a set of EQAS samples. Costs related to the *WADA* assessment(s) shall be at the Laboratory's expense.

A first *WADA* assessment should be conducted at least six (6) months before the scheduled start of the Analytical *Testing* for the Major *Event*. Emphasis will be placed on the completed and planned implementation of the following:

- The physical layout of the Laboratory space to ensure that there is adequate analytical and *Sample* handling capacity (based on the expected number of *Samples* and reporting deadlines), including the separation of analytical and administrative areas of the Laboratory;
- The adequacy of the Laboratory's external and internal security plans, including:
    - Secure Laboratory entry and exit points which are restricted to authorized personnel only;
    - Secure and restricted Laboratory controlled zones (in particular, the analytical area(s), the *Sample* reception/processing room and the *Sample* storage units);
    - Adequate Laboratory space and security measures for the "B" *Sample* opening procedure, including appropriate provisions to ensure the confidentiality of the *Athlete(s)*;
    - 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 point(s) to *Sample* storage room(s) (*e.g.* through the use of CCTV cameras).
- The adequacy of the Laboratory's IT security system, including restricted and secure central server(s), data management system (*e.g.* LIMS), internal network and controlled access to the internet, if applicable;
- The Laboratory's organizational chart for the Major *Event,* which includes the Laboratory staff and planned expansion of staff including external experts. Details shall include names, qualifications, area(s) of operation and responsibilities. In addition, the organizational chart shall identify the Certifying Scientists (internal and external experts) per Analytical *Testing* Procedure;
- The recruitment and logistics plans for the external scientists, including the names, expertise and area(s) of responsibility for the Major *Event*;
- The existing instrumentation and equipment including the plan and timelines to order, install and qualify any new instruments;
- The status of the Laboratory's Analytical *Testing* Procedures, including plans and timelines for method development and validation (including responsible scientific staff) to meet any additional Analytical *Testing* requirements for the Major *Event*;
- The Laboratory's scope of ISO/IEC 17025 accreditation including any planned additions to the scope of accreditation;

- The status of the stock of Reference Materials, including the plans to order and implement any new Reference Materials and/or Reference Collections;
- The Laboratory's internal EQAS program (iQAS), including plans for the conduct of "stress tests". One or more stress tests are recommended to be completed by the time the Laboratory is in its final configuration for the Major *Event*;
- To assess compliance with the ISL and its related *Technical Documents*, Technical Letters and applicable Laboratory Guidelines.

A second *WADA* assessment, if necessary, should be conducted at least two (2) months before the start of Analytical *Testing* for the Major *Event.* At this stage, the Laboratory shall be ready to begin Analytical *Testing* for the Major *Event*, including pre-*Event Testing*, if applicable. The focus of the assessment is to verify that:

- All construction requirements are completed, including any specific measures to ensure the adequacy of the physical layout and the security of the "B" *Sample* opening procedure;
- All measures have been implemented to ensure the adequacy of the Laboratory's IT security system;
- All Analytical Methods are validated and incorporated in the Laboratory's ISO/IEC 17025 scope of accreditation;
- All equipment and supplies are received, including Reference Materials and/or Reference Collections;
- All staff recruitment is completed, including agreements, logistics and schedules for external experts;
- All corrective actions from the prior *WADA* assessment(s) have been satisfactorily addressed;
- The Laboratory has successfully conducted "stress tests" in order to evaluate its readiness for the Major *Event*;
- Any remaining issue(s) will be addressed by the Laboratory before any Major *Event* related Analytical *Testing* is scheduled to begin.

WADA, at its sole discretion and depending on the progress of the Laboratory in preparation for the Major *Event*, may conduct additional assessments of the Laboratory before the scheduled start of the Analytical *Testing* for the Major *Event.*

An Assessment Report will be issued to the Laboratory and the LabEG for each *WADA* assessment. The Assessment Reports may include requests for Corrective Action Reports, Actions and provide guidance as applicable.

The Laboratory shall address and satisfactorily correct all noncompliances identified during the *WADA* assessment(s) and/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.*

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* satisfactory corrective action(s) for any noncompliance(s) identified in 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 should be conducted at a time which includes as many Major *Event* staff (Laboratory staff and temporary external experts) as possible. The EQAS samples shall be analyzed using the same Analytical *Testing* Procedures that will be applied in the analysis of *Samples* for the Major *Event.*

1.3 Pre-*Event* Report

At least two (2) months prior to the start of Analytical *Testing* for the Major *Event*, *WADA* may require that the Laboratory provide a report consisting of the following:

- A valid signed contract between the Laboratory and the responsible *Testing* Authority/*Major Event Organization* including a Test Distribution Plan detailing the *Sample* collection schedule, number of urine and blood *Samples* and requests for specific analyses (*e.g.* EPO);
- An organizational chart including Laboratory staff and temporary scientists employed by the Laboratory for the Major *Event*. Supporting information such as job titles and responsibilities shall be included;
- A list of all senior personnel temporarily working in the Laboratory for the Major *Event* (including name, qualifications and areas(s) of responsibility);
- A training plan with timelines for new staff, including temporary staff and invited external experts. 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;
- 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
- A 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 to the elements included in the Laboratory report shall be immediately reported to *WADA*.

1.4 Additional Professional Liability Insurance Coverage

Laboratories performing Analytical *Testing* during a Major *Event* shall verify their professional liability risk insurance coverage and, if appropriate, obtain complementary coverage to adequately cover liability associated with the analysis of *Samples* and the hiring of additional temporary staff during the Major *Event.*

1.5 "B" Confirmation

The Laboratory shall implement a SOP for conducting "B" Confirmation Procedures, which ensures the maintenance of the *Athlete*'s confidentiality in consideration of the increased media and public attention that might be expected during the Major *Event*. The SOP shall address the following topics:

- An entry and exit plan for *Athletes*, which ensures anonymity from external attention;
- In addition to the requirements of ISL Article 5.3.6.2.3, a representative from *WADA* or *WADA*'s Independent Observers (IO) Team for Major *Events* (if requested by *WADA* or the IO team, respectively) shall be authorized to attend the "B" *Sample* Confirmation Procedure;
- The scheduling of the "B" *Sample* Confirmation Procedure shall be made as soon as possible, in consultation with the *Major Event Organizer*, and taking into account that postponement could significantly increase the risk of *Sample* degradation and/or inadequately delay the decision-making process in the given circumstances.

1.6 Documentation and Reporting

The reporting time required for Major *Events* may be substantially less than twenty (20) days (see also ISL Article 5.3.8.4). The agreement between the Laboratory and the *Major Event Organization* shall clarify the reporting timelines for Negative Findings, *Adverse Analytical Findings*, *Atypical Findings* and the reporting of specific test results (*e.g.*, GC/C/IRMS, EPO).

2.0 Major *Event* Analytical *Testing* in "Satellite" Laboratory Facilities

In addition to the accreditation requirements for Major *Events* listed in Annex B Art 1.0, a Laboratory which is required to move or extend its operations temporarily to a new physical location ("satellite facility"), shall also meet the following requirements:

2.1 Participating in *WADA* Assessment(s)

WADA shall perform assessment(s) (preferably on-site) of the "satellite facility". The number and type of assessments (on-site, remote and/or documentary audit) will be determined by *WADA* based on the scale of the Major *Event*'s Test Distribution Plan and the Laboratory's progress in preparing for the Major *Event.* These assessment(s) may include analysis of a set of EQAS samples. Expenses related to such visit(s) shall be at the Laboratory's expense.

2.1.1 Initial *WADA* Assessment

WADA may perform an initial assessment of the Laboratory "satellite facility" as soon as it is available in order to determine whether the new facility is adequate in relation to the expected security, analytical and *Sample* handling requirements for a Major *Event*. 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 ISO/IEC 17025.

2.2 Documenting ISO/IEC 17025 Accreditation of the 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 has approved the continued accreditation or accepted the suitability of the "satellite facility". An ISL trained assessor shall participate in the Accreditation Body assessment of the "satellite facility".

2.3 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.*

2.4 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.*

All Test 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 assessment for *WADA* accreditation. Any changes to Test Methods, equipment or other procedures in the Management System shall also be validated prior to the assessment.

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 a Temporary and Limited *WADA* Accreditation Certificate for the period of the Major *Event*, which includes an appropriate time before and after the duration of the Major *Event.*

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

3.0 Monitoring and Assessment during a Major *Event*

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).

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

3.1 Reporting of *False Analytical Findings* during a Major *Event*

In the event of a False *Adverse Analytical Finding*, the Laboratory shall immediately cease Analytical *Testing* for the relevant 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.

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.

ISL ANNEX C – 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 challenges a recommendation of the LabEG in accordance with ISL Articles 4.6.4.1.2 or 4.6.4.5, when a Laboratory is subject to Revocation proceedings in accordance with ISL Article 4.6.4.3 or, when and where applicable, Disciplinary Proceedings are instituted against an *ABP* Laboratory in accordance with ISL Article 4.7.4.1. In such circumstances, any reference made to a Laboratory in these Procedural Rules shall also be understood as a reference to an *ABP* Laboratory, unless such reference is not applicable due to the circumstances, specific nature or rules indicated in this ISL in relation to *ABP* Laboratories.

These Procedural Rules shall be considered as an integral part of the ISL.

PART I - Composition of the Committee

Article 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 select one member to serve as Chairperson.

The appointed members shall have a legal and/or scientific background with at least one member being an anti-doping laboratory expert and one with legal training and education (including the Chairman). The Chairman shall have experience in the conduct of disciplinary or legal proceedings.

All appointed members of a 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 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 agree to maintain the confidentiality of the disciplinary process and any information related thereto, confirm their impartiality and mention any circumstance that may be relevant in this respect.

Article 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/she 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 final decision. The decision is not subject to an independent challenge.

PART II - General Provisions

Article 3

Once the DC is constituted, *WADA* will provide it with the case file which includes 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 relevant information to the DC electronically or by registered mail.

Simultaneously, *WADA* shall provide the Laboratory with the 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.

Within seven (7) days of receiving the case file, the Laboratory may respond in writing and provide its evidence to the DC and simultaneously to *WADA*'s Legal Department. Any requests to extend the 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.

Upon receipt of the Laboratory's submissions and evidence, *WADA* shall have seven (7) days to make rebuttal submissions to the Disciplinary Committee. Any requests by *WADA* to extend this deadline shall be addressed to the Chairperson of the DC, who shall have the discretion to grant or reject the requested extension.

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.

Article 4

Unless both parties agree or the Chairperson, at his/her discretion and following consultation with the other DC members, orders otherwise on the basis of justified grounds, the parties shall not be permitted to include additional material after the submission of the evidence packages in accordance with the procedure described in Annex C Article 3 above. Any determination made by the Chairperson pursuant to this article is not subject to challenge or appeal.

Article 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

Article 6

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.

To the extent not otherwise provided in these "Procedural Rules", the Chairperson may issue directions regarding procedural matters to the parties.

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.

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.

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.

The DC's decisions, including the content of its recommendation, shall be by majority.

PART IV - Recommendation

Article 7

The recommendation of the DC shall be issued in writing, with reasons [33], within fourteen (14) days of the conclusion of the hearing. If no hearing is held, the DC shall issue its recommendation within fourteen (14) days of the communication to the parties that no hearing will be held.

Where the DC considers that a Laboratory's accreditation should be suspended or subject to an Analytical *Testing* Restriction, it shall recommend to the Chair of the *WADA* Executive Committee 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*.

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 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 *WADA.* The DC shall also indicate any conditions that the Laboratory shall satisfy prior to or after reinstatement of the Laboratory's *WADA* accreditation.

In cases where it considers that it is appropriate to do so, the DC may also recommend to the Chair of the *WADA* Executive Committee that the Laboratory receive a private warning without the imposition of a period of Suspension or Analytical *Testing* Restriction. The Laboratory may also be requested to take

[33] The decision may be summarily reasoned.

specified action(s) to resolve the issues identified within a defined timeline.

The recommendation of the DC shall be provided to the Chair of the *WADA* Executive Committee without delay.

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) days of receiving the DC's recommendation.

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 fourteen (14) days of receiving the DC's recommendation.

If the DC recommends to the Chair of the *WADA* Executive Committee that the Laboratory shall maintain its *WADA* accreditation, and the Chair of the *WADA* Executive Committee accepts the DC's recommendation, the Laboratory shall be informed accordingly by *WADA* within seven (7) days of receiving the Chair of the *WADA* Executive Committee's decision.

Part V – Expedited Proceedings or Single Hearing before *CAS*

Article 8

Where required by the circumstances, the DC may, at the request of *WADA* or the Laboratory, conduct disciplinary proceedings in an expedited manner. In such situations, the DC may issue appropriate directions and modify the timelines indicated in these Procedural Rules as required and justified by the circumstances, but must ensure that the principles of procedural fairness, and the requirements otherwise stated in these Procedural Rules, are respected at all times.

The decision to conduct disciplinary proceedings in an expedited manner shall be at the sole discretion of the DC and shall not be subject to appeal.

If required due to time constraints, the DC may issue an operative recommendation to the Chairman of the *WADA* Executive Committee or the *WADA* Executive Committee, as applicable, with reasons to follow.

In cases of a Suspension or an Analytical *Testing* Restriction, the Chairman of the *WADA* Executive Committee or, in cases of Revocation, the *WADA* Executive Committee, shall endeavor to render a decision regarding the status of the Laboratory's *WADA* accreditation as soon as reasonably possible. Once received, *WADA* shall provide the decision to the Laboratory without delay.

[Comment: The Laboratory or WADA may request that disciplinary proceedings be conducted in an expedited manner if a decision regarding the status of the Laboratory's WADA accreditation must be made shortly prior to the commencement of a Major Event or Event or if otherwise justified by the circumstances.]

Article 9

The Laboratory and *WADA* may agree to have the assertion of a noncompliance(s) with the ISL and/or *Technical Document(s)* and/or Technical Letters heard in a single hearing directly before a three (3)-

member Panel of the *CAS* Anti-Doping Division in accordance with the Arbitration Rules for the *CAS* Anti-Doping Division.

With the consent of *WADA* and the Laboratory, the proceedings may be conducted in an expedited manner in accordance with the Arbitration Rules for the *CAS* Anti-Doping Division.