WORLD ANTI-DOPING CODE

INTERNATIONAL STANDARD

LABORATORIES

NOVEMBER 2019

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International Standard for Laboratories

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

The International Standard for Laboratories first came into effect in November 2002. Further revisions were made after that date. The enclosed International Standard for Laboratories was approved by the *WADA* Executive Committee on 15 May 2019. The effective date of ISL version 10.0 is 01 November 2019.

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

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Table of Contents

PART ONE: INTRODUCTION, *CODE* PROVISIONS AND DEFINITIONS

1.0 Introduction, Scope and References

1.1 The ISL and the World Anti-Doping Program

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

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

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

> "*International Standards* for different technical and operational areas within the anti-doping program have been and will be developed in consultation with the *Signatories* and governments and approved by *WADA*. The purpose of the *International Standards* is harmonization among *Anti-Doping Organizations* responsible for specific technical and operational parts of anti-doping programs. Adherence to the *International Standards* is mandatory for compliance with the *Code*. The *International Standards* may be revised from time to time by the *WADA* Executive Committee after reasonable consultation with the *Signatories*, governments and other relevant stakeholders. *International Standards* and all revisions will be published on the *WADA* website and shall become effective on the date specified in the *International Standard* or revision."

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

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

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

1.2 *WADA* Laboratory Standards

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

1.2.1 Technical Documents

- Technical Documents are issued to provide direction to the Laboratories, WADA-Approved Laboratories for the ABP and other stakeholders on specific technical or procedural issues. Technical Documents are modified and/or withdrawn by *WADA* as appropriate.
- Technical Documents are approved by the *WADA* Executive Committee and published on *WADA*'s website. Once approved, a Technical Document supersedes any previous publication on a similar topic [1] and becomes an integral part of 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 [2].
- The implementation of the requirements of *WADA* Technical Documents into the Laboratory's and, if relevant to the analysis of *ABP* blood *Sample*s, WADA-Approved Laboratory for the ABP's Management System is mandatory for obtaining and maintaining *WADA* accreditation or approval, respectively, and for the application of the relevant Analytical Testing Procedure(s) to the analysis of *Samples*.

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

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

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

- In cases when a newly approved version of a Technical Document lowers either the Decision Limit for a Threshold Substance or the reporting limit for a Non-Threshold Substance, as applicable, the revised limits specified in the new Technical Document shall not be applied to the reporting of analytical results for *Samples* collected before the effective date of the Technical Document [3].
- The most recently approved Technical Document shall be applied to Analytical Testing of *Samples* if it would lead to a result that benefits the *Athlete* (*e.g.* increase of the Decision Limit for a Threshold Substance or of the reporting limit for a Non-Threshold Substance, establishment of more stringent identification criteria for chromatographic-mass spectrometric or electrophoretic Confirmation Procedures). Therefore, in the case where an analytical finding does not meet the reporting criteria defined in the new Technical Document, it shall be reported as a Negative Finding.
- Subject to the above, the analysis of *Samples* or the review of analytical data may occur immediately once a Technical Document has been approved.

1.2.2 Technical Letters

- Technical Letters are issued in letter format on an *ad-hoc* basis in order to provide direction to the Laboratories, WADA-Approved Laboratories for the ABP and other stakeholders on particular issues on the analysis, interpretation and reporting of results for specific *Prohibited Substance*(s) and/or *Prohibited Method*(s) or on the application of specific Laboratory procedures. Technical Letters are modified and/or withdrawn by *WADA* as appropriate.
- Technical Letters are approved by the *WADA* Executive Committee and published on *WADA*'s website. Technical Letters become effective immediately, unless otherwise specified by *WADA* [4].
- Once approved, a Technical Letter supersedes any previous publication on a similar topic [1] and becomes an integral part of the ISL.

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[3] If the application of a newly approved Technical Document results in an *Adverse Analytical Finding* for a *Sample* collected before the effective date of that new Technical Document, which would not have resulted in an *Adverse Analytical Finding* with the application of the currently effective version of the Technical Document (for example if the Decision Limit for a Threshold Substance has been lowered in the newly approved Technical Document), the Laboratory shall report the finding as a Negative Finding. In addition, the Laboratory shall record the details of the finding as a comment in the Negative Finding Test Report.

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

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

- The implementation of the requirements of relevant Technical Letters into the Laboratory's and, if relevant to the analysis of *ABP* blood *Sample*s, WADA-Approved Laboratory for the ABP's Management System is mandatory for obtaining and maintaining *WADA* accreditation or approval, respectively, and for the application of the relevant Analytical Testing Procedure(s) to the analysis of *Samples.*

1.2.3 Laboratory Guidelines

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

1.2.4 Technical Notes

- Technical Notes are issued to Laboratories to provide detailed technical guidance on the performance of specific Analytical Methods or procedures.
- Technical Notes are approved by the *WADA* LabEG. Technical Notes are provided to Laboratories only and are not published on *WADA*'s website.
- Implementation of the recommendations detailed in Technical Notes is not mandatory. However, Laboratories are encouraged to follow, to the fullest extent possible, the technical guidance included in Technical Notes.

1.3 *Sample* Analysis

Sample analysis is part of the Analytical Testing process and involves the detection, identification, and in some cases demonstration of the presence 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 undertake other forms of analysis, subject to the provisions of the Code of Ethics (see Annex A of the ISL), 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, Laboratory Test Reports, Certificates of Analysis or other documentation or correspondence shall not declare or represent that any such testing is covered under the Laboratory's *WADA* accreditation status.

WADA-Approved Laboratories for the ABP may undertake other forms of analyses, which are not within the scope of the *WADA* approval (*e.g.* forensic testing, clinical testing, drugs of abuse testing). For the avoidance of doubt, Test Reports, Certificates of Analysis or other documentation or correspondence

from WADA-Approved Laboratories for the ABP shall not state or represent that any such testing is covered under their *WADA* approval status.

1.4 Laboratory Accreditation Framework and Laboratory Approval for the *ABP*

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

- Part Two of the ISL describes the requirements necessary to obtain and maintain *WADA* accreditation and the procedures involved to fulfill these requirements (Section 4). It also includes the application of ISO/IEC 17025 [5] to the field of *Doping Control* (Section 5) and a description of the *WADA* External Quality Assessment Scheme (EQAS) (Section 6) as well as the procedures to evaluate the Laboratory EQAS and routine Analytical Testing performance by *WADA* (Section 7). The purpose of this Part of the document is to enable the consistent application of ISO/IEC 17025 and ISL-specific requirements to Analytical Testing for *Doping Control* by Laboratories, as well as to facilitate the assessment of Laboratory compliance by Accreditation Bodies and *WADA*.

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

- Part Three of the ISL includes all Annexes. Annexes A (Code of Ethics) and B (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*.

In order to harmonize the accreditation of Laboratories to the requirements of ISO/IEC 17025 and of WADA-Approved Laboratories for the ABP to the requirements of ISO/IEC 17025 or ISO 15189, as well as the *WADA*-specific requirements for accreditation 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.

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

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Terms defined in the *Code*, which are included in this standard, are written in *Italics*.
Terms, which are defined in the ISL or other *International Standards*, are underlined.
Other terms are used in the ISL and other *WADA* Laboratory standards as follows:

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

[5] Effective version of ISO/IEC 17025.

2.0 *Code* Provisions

The following Articles in the *Code* are addressed in the ISL:

- *Code* Art. 2 ANTI-DOPING RULE VIOLATIONS
- *Code* Art. 3 PROOF OF DOPING
- *Code* Art. 4 THE *PROHIBITED LIST*
- *Code* Art. 6 ANALYSIS OF *SAMPLES*
- *Code* Art. 10 SANCTIONS ON INDIVIDUALS
- *Code* Art. 13 APPEALS
- *Code* Art. 14 CONFIDENTIALITY AND REPORTING

3.0 Terms and Definitions

3.1 *Code* defined terms

ADAMS	The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and *WADA* in their anti-doping operations in conjunction with data protection legislation.
Adverse Analytical Finding	A report from a *WADA*-accredited laboratory or other *WADA*-approved laboratory that, consistent with the *International Standard* for Laboratories and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (including elevated quantities of endogenous substances) or evidence of the *Use* of a *Prohibited Method*.
Adverse Passport Finding	A report identified as an *Adverse Passport Finding* as described in the applicable *International Standards*.
Anti-Doping Organization	A *Signatory* that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events*, *WADA*, International Federations, and *National Anti-Doping Organizations.*
Athlete	Any *Person* who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each *National Anti-Doping Organization).* An *Anti-Doping Organization* has discretion to apply anti-doping rules to an *Athlete* who is neither an *International-Level Athlete* nor a *National-Level Athlete*, and thus to bring them within the definition of "Athlete." In relation to *Athletes* who are neither *International-Level* nor *National-Level Athletes*, an *Anti-Doping Organization* may elect to: conduct limited *Testing* or no *Testing* at all; analyze *Samples* for less than the full menu of *Prohibited Substances*; require limited or no whereabouts information; or not require advance *TUEs*. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any *Athlete* over whom an *Anti-Doping Organization* has authority who competes below the international or national level, then the *Consequences* set forth in the *Code* (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*. [Comment: This definition makes it clear that all International- and National-Level *Athletes* are subject to the anti-doping rules of the *Code*, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and *National Anti-Doping Organizations*, respectively. The definition also allows each *National Anti-*

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

Athlete Biological Passport (*ABP*)	The program and methods of gathering and collating data as described in the International Standard for Testing and Investigations and International Standard for Laboratories.
Atypical Finding	A report from a *WADA*-accredited laboratory or other *WADA* approved laboratory, which requires further investigation as provided by the International Standard for Laboratories or related Technical Documents prior to the determination of an *Adverse Analytical Finding*.
Atypical Passport Finding	A report described as an *Atypical Passport Finding* as described in the applicable *International Standards.*
CAS	The Court of Arbitration for Sport
Code	The World Anti-Doping Code.
Competition	A single race, match, game or singular sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other sport contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.
Consequences of Anti-Doping Rule 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 or Public*

	Reporting means the dissemination or distribution of information to the general public or *Persons* beyond those *Persons* entitled to earlier notification in accordance with Article 14. Teams in *Team Sports* may also be subject to *Consequences* as provided in Article 11.
Doping Control	All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, *TUE*s, results management and hearings.
Event	A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).
In-Competition	Unless provided otherwise in the rules of an International Federation or the ruling body of the *Event* in question, "*In-Competition"* means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*. [Comment: An International Federation or ruling body for an *Event* may establish an "*In-Competition*" period that is different than the *Event* Period.]
Ineligibility	See *Consequences of Anti-Doping Rule Violations* above.
International Standard	A standard adopted by *WADA* in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standard*s shall include any Technical Documents issued pursuant to the *International Standard.*
Major Event Organizations	The continental associations of *National Olympic Committee*s and other international multi-sport organizations that function as the ruling body for any continental, regional or other *International Event*.
Marker	A compound, group of compounds or biological variable(s) that indicates the *Use* of a *Prohibited Substance* or *Prohibited Method.*
Metabolite	Any substance produced by a biotransformation process.
National Anti-Doping Organization	The entity(ies) designated by each country as possessing the primary authority and responsibility to adopt and implement anti-doping rules, direct the collection of *Samples*, the management of test results, and the conduct of hearings at the national level. If this designation has not been made by the competent public authority(-ies), the entity shall be the country's *National Olympic Committee* or its designee.

National Olympic Committee	The organization recognized by the International Olympic Committee. The term *National Olympic Committee* shall also include the National Sport Confederation in those countries where the National Sport Confederation assumes typical *National Olympic Committee* responsibilities in the anti-doping area.
Out-of-Competition	Any period which is not *In-Competition*.
Person	A natural *Person* or an organization or other entity.
Prohibited List	The List identifying the *Prohibited Substances* and *Prohibited Methods*.
Prohibited Method	Any method so described on the *Prohibited List*.
Prohibited Substance	Any substance, or class of substances, so described on the *Prohibited List*.
Publicly Disclose or Publicly Report	See *Consequences of Anti-Doping Rule Violations* in the *Code*. "The dissemination or distribution of information to the general public or *Persons* beyond those *Persons* entitled to earlier notification in accordance with Article 14. Teams in *Team Sports* may also be subject to *Consequences* as provided in Article 11."
Sample or *Specimen*	Any biological material collected for the purposes of *Doping Control*.
Signatories	Those entities signing the *Code* and agreeing to comply with the *Code*, as provided in Article 23.
Tampering	Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly; obstructing, misleading orengaging in any fraudulent conduct to alter results or prevent normal procedures from occurring.
Target Testing	Selection of specific *Athletes* for *Testing* based on criteria set forth in the International Standard for Testing and Investigations.
Testing	The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the laboratory.
TUE	Therapeutic Use Exemption, as described in Article 4.4.
Use	The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method.*
WADA	The World Anti-Doping Agency.

3.2 ISL Defined Terms

Adaptive Model	A mathematical model designed to identify unusual longitudinal results from *Athletes*. The model calculates the probability of a longitudinal profile of *Marker* values, assuming that the *Athlete* has a normal physiological condition.
Aliquot	A portion of the *Sample* of biological fluid (*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, which is 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	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.
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 and its associated uncertainty.
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 preventive actions adopted to minimize the risk of recurrence of the nonconformity.
Decision Limit (DL)	The value of the result for a Threshold Substance in a *Sample*, obtained using a validated measurement procedure, above which it can be concluded that the Threshold has been exceeded with a statistical confidence of at least 95% [see Technical Document on Decision Limits for the Confirmatory Quantification of Threshold Substances (TD DL)].
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 WADA-Approved Laboratories for the ABP 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 or WADA-Approved Laboratory for the ABP to make and implement restricted modifications in the Scope of ISO/IEC 17025 Accreditation, as applicable, prior to the assessment by the Accreditation Body. See ISL Art. 4.4.2.2 for a detailed description of Flexible Scope of ISO/IEC 17025 Accreditation.
Further Analysis	Further Analysis means any additional Analytical Testing performed on a *Sample* whether using the same Analytical Method(s) or any new or additional Analytical Testing Procedure(s) (for example, new or more sensitive Analytical Methods or Analytical Methods used to identify additional Analytes). [Prior to reporting a test result, a Laboratory may perform Further Analysis on a *Sample* with no approval required. After reporting a test result, Further Analysis may be performed at any time by the same Laboratory that did the original Analytical Testing or by a different Laboratory or other *WADA*-approved laboratory, at the direction of the *Anti-Doping Organization* that initiated and directed *Sample* collection or *WADA.* Any other *Anti-Doping Organization* that wishes to conduct Further Analysis on a stored *Sample* may do so with the permission of the *Anti-Doping Organization* that initiated and directed *Sample* collection or *WADA* and shall be responsible for any follow-up results management. Any *Sample* storage or Further Analysis initiated by

	WADA or another *Anti-Doping Organization* shall be at *WADA*'s or that Organization's expense].
Identification Capability	Analytical parameter of assay technical performance. Lowest estimated concentration at which a Confirmation Procedure is capable of consistently identifying (*i.e.* confirming under the stated test conditions) an Analyte, for which a Reference Material is available, according to the criteria established in the Technical Document on Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for *Doping Control* Purposes (TD IDCR). The Identification Capability of a Laboratory cannot be higher than the MRPL; however, it may be lower. The Identification Capability is also referred to as the Limit of Identification (LOI).
Independent Witness	A *Person*, invited by the Testing Authority, the Laboratory or *WADA* to witness parts of the Analytical Testing process. The Independent Witness shall be independent of the *Athlete* and his/her representative(s), the Laboratory, the Sample Collection Authority, the Testing Authority / Results Management Authority or *WADA*, as applicable. The Independent Witness may be indemnified for his/her service.
Initial Testing Procedure (ITP)	An Analytical Testing Procedure whose purpose is to identify those *Samples* which may contain a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* or an elevated quantity of a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker*(s) of the *Use* of a *Prohibited Substance* or *Prohibited Method*.
Intermediate Precision (s_w)	Variation in results observed when one or more factors, such as time, equipment, or operator are varied within a Laboratory. It is also referred to as inter-batch / inter-run precision.
International Standard for Laboratories (ISL)	The *International Standard* applicable to Laboratories and WADA-approved Laboratories for the ABP.
Laboratory Internal Chain of Custody	Documentation maintained within the Laboratory to record the chronological traceability of custody (by *Person(s)* or upon storage) and actions performed on the *Sample* and any Aliquot of the *Sample* taken for Analytical Testing. [Laboratory Internal Chain of Custody is generally documented by a written or electronic record of the date, location, action taken, and the *Person* performing an action with a *Sample* or Aliquot.]
Laboratory(-ies)	(A) *WADA*-accredited laboratory(-ies) applying Test Methods and processes to provide evidentiary data for the detection and/or identification of *Prohibited Substances* or *Prohibited Methods* on the *Prohibited List* and, if applicable, quantification of a Threshold Substance in *Samples* of urine and other biological matrices in the context of *Doping Control* activities.

Laboratory Guidelines	Recommendations of Laboratory best practice provided by *WADA* to address specific Laboratory operations or to provide technical requirements and guidance on interpretation and reporting of results for the analysis of specific *Prohibited Substance*(s) and/or *Prohibited Method*(s) or on the application of specific Laboratory procedures. [Laboratory Guidelines are posted on *WADA*'s website, are not of mandatory application and may be later incorporated, partially or in full, in Technical Document(s) or in the ISL. Laboratory Guidelines are approved by the *WADA* Laboratory Expert Group].
Laboratory Documentation Package	The material produced by the Laboratory to support an analytical result such as an *Adverse Analytical Finding* as set forth in the *WADA* Technical Document for Laboratory Documentation Packages (TD LDOC).
Limit of Detection (LOD)	Analytical parameter of assay technical performance. Lowest concentration of an Analyte in a *Sample* that can be routinely detected, but not necessarily identified or quantified, under the stated test conditions.
Limit of Identification (LOI)	Identification Capability
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 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) and for which a significant increase of resources and capacity may be required to conduct *Doping Control* for the *Event*.
Measurement Uncertainty (MU)	Parameter associated with a measurement result that characterizes the dispersion of quantity values attributed to the measure and provides confidence in the validity of the measured result [see Technical Document on Decision Limits for the Confirmatory Quantification of Threshold Substances (TD DL)].
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 for detection and identification of Non-Threshold Substances (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 the Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for *Doping Control* Purposes (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 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.
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 only the substance of interest, without interferences from the matrix or from other substance(s) present in the *Sample*.
Suspension	The temporary withdrawal of a Laboratory's *WADA* accreditation.
Technical Document	Technical requirements produced by *WADA* on specific anti-doping topics. Technical Documents supersede any previous publication on a similar topic, or, if applicable, the ISL. [Implementation of the requirements described in a Technical Document is mandatory. Technical Documents are approved by the *WADA* Executive Committee and posted on *WADA*'s website. All Laboratories and WADA-Approved Laboratory for the ABP shall have the requirements of a Technical Document implemented in their procedures no later than its "effective date"].
Technical Letter	Mandatory technical requirements provided by *WADA* in letter format from time to time (*ad-hoc*) to address particular issues on the analysis, interpretation and reporting of specific *Prohibited Substance*(s) and/or *Prohibited Method*(s) or on the application of specific Laboratory or WADA-Approved Laboratory for the ABP procedures. [Technical Letters are approved by the *WADA* Executive Committee, and become effective immediately, unless otherwise specified by *WADA*].
Technical Note	Technical guidance provided by *WADA* to Laboratories on the performance of specific Laboratory methods or procedures. [Technical Notes are not considered part of Technical Documents and therefore are not of mandatory application. Technical Notes are approved by the *WADA* Laboratory Expert Group and become effective immediately].
Test Method	Analytical Testing Procedure, Analytical Method.
Threshold	The maximum permissible level of the concentration, ratio or score for a Threshold Substance in a *Sample*. The Threshold is used to establish the Decision Limit for reporting an *Adverse Analytical Finding* or *Atypical Finding* for a Threshold Substance.
Threshold Substance	An exogenous or endogenous *Prohibited Substance, Metabolite* or *Marker* of a *Prohibited Substance* for which the identification and quantitative determination (*e.g.* concentration, ratio, score) in excess of a pre-determined Decision Limit, or, when applicable, the establishment of an exogenous origin, constitutes an *Adverse Analytical Finding*. Threshold Substances are identified as such in the Technical Document on Decision Limits (TD DL).
WADA-Approved Laboratory(-ies) for the ABP	Laboratory(-ies), not otherwise accredited by *WADA,* which apply Analytical Methods and processes in support of the hematological module of the *ABP* program and in accordance with the criteria for approval of non-accredited laboratories for the *ABP*.

3.3 International Standard for Testing and Investigations (ISTI) Defined Terms

Results Management Authority	The organization that is responsible, in accordance with *Code* Art. 7.1, for the management of the results of *Testing* (or other evidence of a potential anti-doping rule violation) and hearings, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, *WADA*, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization acting pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation). In respect of Whereabouts Failures, the Results Management Authority shall be as set out in Art. I.5.1.
Sample Collection Authority	The organization that is responsible for the collection of *Samples* in compliance with the requirements of the International Standard for Testing and Investigations, whether (1) the Testing Authority itself; or (2) another organization (for example, a third party contractor) to whom the Testing Authority has delegated or subcontracted such responsibility (provided that the Testing Authority always remains ultimately responsible under the *Code* for compliance with the requirements of the International Standard for Testing and Investigations relating to collection of *Samples*).
Sample Collection Session	All of the sequential activities that directly involve the *Athlete* from the point that initial contact is made until the *Athlete* leaves the Doping Control Station after having provided his/her *Sample*(s).
Suitable Volume of Urine for Analysis	A minimum of 90 mL, whether the Laboratory will be analyzing the *Sample* for all or only some *Prohibited Substances* or *Prohibited Methods*.
Test Distribution Plan	A document written by an *Anti-Doping Organization* that plans *Testing* on *Athletes* over whom it has Testing Authority, in accordance with the requirements of Art. 4 of the International Standard for Testing and Investigations.
Testing Authority	The organization that has authorized a particular *Sample* collection, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or other *Major Event Organization*, *WADA*, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization conducting *Testing* pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation).

PART TWO: LABORATORY ACCREDITATION REQUIREMENTS AND OPERATING STANDARDS

4.0 Process and Requirements for *WADA* Laboratory Accreditation

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

4.1 Applicant Laboratory

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

4.1.1 Expression of Interest

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 the 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 entities 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 *Signatory, Code*-compliant (as determined by *WADA*) *Anti-Doping Organizations* such as a *National Anti-Doping Organization* or *Regional Anti-Doping Organization*

responsible for a National Anti-Doping Program, or an International Federation responsible for an International Anti-Doping Program. Such letter(s) of support shall indicate a commitment to provide the Laboratory with a minimum of 3,000 *Samples* [6] per year within two (2) years of obtaining *WADA* accreditation;

- A declaration by the supporting *Anti-Doping Organization*(s) that their relationship with the applicant laboratory is compliant with ISL Art. 4.2.3.

4.1.4 Provision of Business Plan

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

4.2 Candidate Laboratory

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

4.2.1 Description of the Candidate Laboratory

Once approved by the *WADA* Executive Committee, the candidate laboratory shall 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 a secure laboratory environment (*e.g.,* CCTV monitoring, restricted access to sample storage areas);
  - IT Security: implementation of firewalls and other cyber security measures consistent with best practice and any applicable governmental regulations (see ISL Arts. 5.2.3.4.1 and 5.2.3.4.2);
  - Information Technology (IT) infrastructure: implementation of a data and information management system (*e.g.* LIMS), central server/intranet which allows secure data handling (see ISL Arts. 5.2.3.4.3 and 5.2.3.4.4).

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

- List of actual and proposed instrumental resources and equipment, including year of purchase and conditions for instrument technical support (access to 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;
- List of laboratory sponsors;
- Contract or Memorandum of Understanding with a WADA-accredited Laboratory, which will provide mentoring and training for at least the period spanning the probationary phase of accreditation;
- Status of ISO/IEC 17025 accreditation;
- Description of customs regulations in the host country with respect to the reception of urine and blood samples, Reference Materials and consumables from abroad and the ability to ship *Samples* outside the country as needed; and
- Letter of compliance with the Code of Ethics (ISL Annex A) signed by the laboratory Director.

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

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 Laboratory Independence and Impartiality

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

- Administrative independence requires that the laboratory is a separate legal entity without any administrative links to an *Anti-Doping Organization* or other sport or political organizations;
- Operational independence requires that the laboratory shall manage its own affairs without hindrance, interference or direction from any *Anti-Doping Organization*, sport organizations or any *Person*. This requires the laboratory to have a dedicated budget allowing the implementation of an efficient approval process for the timely procurement of necessary Reference Materials, reagents, consumables and essential equipment, as well as independent laboratory management decisions concerning the recruitment, retention and training of staff, participation in scientific meetings and symposia, etc. This does not prevent the laboratory from receiving research grants or other financial

support from their host organization (*e.g*. university, hospital, public institution), *Anti-Doping Organizations*, sport organizations, government, or other sponsors, and following applicable accounting regulations in connection with the receipt and management of those funds.

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

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

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.

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

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

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

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

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

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

application and may affect the timeliness of the candidate laboratory's entry into the probationary phase of accreditation.

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

4.2.5.6 Upon satisfactory completion of the candidate laboratory requirements (as per ISL Art. 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

4.3.1 Obtaining ISO/IEC 17025 Accreditation by the Laboratory

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 ISL Section 5). 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 ISL Section 5). 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.

4.3.2 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 ISL Section 6 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 ISL Art. 6.4 within a period determined by *WADA*. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in ISL Sections 6 and 7, respectively.

4.3.3 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 *Code*-compliant *Anti-Doping Organizations*.

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

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

4.3.4 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 (ISL Annex A).

4.3.5 Professional Liability Insurance Coverage

Before *WADA* grants accreditation, probationary 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.

4.4 *WADA*-Accredited Laboratory

4.4.1 Obtaining *WADA* accreditation

4.4.1.1 *WADA* Accreditation Assessment

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

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

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

4.4.1.1.3 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.

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

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

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

4.4.1.1.6 After receiving the FAT EQAS results, *WADA* shall inform the probationary laboratory of the evaluation of its performance. Corrective actions, if any, shall be conducted and reported by the probationary laboratory to *WADA* within thirty (30) calendar days, or as otherwise indicated by *WADA*.

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

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

4.4.1.2 *WADA* Recommendation for Accreditation

4.4.1.2.1 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 make a final recommendation concerning the accreditation of the probationary laboratory.

Once all accreditation requirements have been satisfactorily met by the probationary laboratory, the LabEG will submit its recommendation to grant *WADA* accreditation of the laboratory 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 on-site assessment, as determined by *WADA,* may be required and conducted at the probationary laboratory's expense. A probationary laboratory that fails to provide satisfactory improvements, as determined by the LabEG, after six (6) months may be required to renew its candidacy as described in ISL Art. 4.2 or to re-start the probationary phase of accreditation in accordance with ISL Art. 4.3.

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

4.4.1.3 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* (ISL Section 5), granted by a relevant Accreditation Body, which is an ILAC full member and signatory to the ILAC MRA.

4.4.2.2 Flexible Scope of ISO/IEC 17025 Accreditation

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 [8].

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

- New Analytical Testing Procedures: Any Analytical Testing Procedure, which is new to the field of anti-doping analysis, shall be approved as Fit-for-purpose by *WADA* prior to implementation by any

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

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 Laboratory shall obtain an extension of the Scope of ISO/IEC 17025 Accreditation by the relevant Accreditation Body and may be required to successfully participate in a *WADA* EQAS, if available.

- *WADA*-specific Analytical Testing Procedures: *WADA* may require an extension of the Scope of ISO/IEC 17025 Accreditation to include specific Analytical Testing Procedures before application to the analysis of *Samples*, even if the analytical technique involved is already incorporated in the Laboratory's Scope of ISO/IEC 17025 Accreditation. Therefore, these Analytical Testing Procedures are not eligible for the analysis of *Samples* within a flexible Scope of ISO/IEC 17025 Accreditation. *WADA* will communicate which Analytical Testing Procedures are included in this category to the Laboratories and to the Accreditation Bodies. In such cases, the Analytical Testing Procedure shall be validated by the Laboratory, and the Laboratory may be required to successfully participate in an inter-laboratory collaborative study or *WADA*-organized EQAS round in order to obtain an extension to the Scope of ISO/IEC 17025 Accreditation by a relevant Accreditation Body before applying the Analytical Testing Procedure to the analysis of *Samples*. However, once included within the scope, limited changes to these Analytical Testing Procedures may be allowed under a Flexible Scope of ISO/IEC 17025 Accreditation.

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

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

4.4.2.3 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 ISL Section 6.

4.4.2.4 Laboratory Independence and Impartiality

The Laboratory shall strictly maintain its full administrative and operational independence and impartiality at all times (see ISL Art. 4.2.3) [9].

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

If the Laboratory's investigation determines that a breach of the Code of Ethics occurred, the Laboratory Director shall immediately inform *WADA* of the results of the investigation and the disciplinary actions taken. *WADA* may also request further sanctions or implement sanctions as a result of its own investigations. Sanctions may range from a personal reprimand to the expulsion of the implicated Laboratory staff member(s), the reporting of the breach to the pertinent authorities (*e.g.* law enforcement) or even the Suspension or Revocation of the Laboratory's *WADA* accreditation.

4.4.2.6 Document Implemented Research and Development Activities

The Laboratory shall maintain a plan for research and development in the field of 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 *Code*-compliant *Anti-Doping Organizations*.

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

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

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

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

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 (ISL Annex A).

4.4.2.8 Maintain Professional Liability Insurance Coverage

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

4.4.2.9 Maintain Minimum Number of *Samples*

In order to maintain proficiency in Analytical Testing, Laboratories are required to analyze a minimum of 3,000 *Samples* [11] provided annually by *Signatory, Code*-compliant *Anti-Doping Organizations* (as determined by *WADA*) or as otherwise approved by *WADA*.

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

When an *Anti-Doping Organization* is declared non-compliant with the *Code* by *WADA*, it is recognized that this may affect a Laboratory's ability to analyze a minimum of 3,000 *Samples* annually. In such cases, *WADA* shall require that the Laboratory implements measures to maintain proficiency in Analytical Testing, for example by strengthening its internal Quality Assurance Scheme (iQAS) and internal audits program. *WADA* may also provide additional EQAS samples and/or conduct a document audit and/or an on-site assessment, at its discretion, in order to assess the status of the Laboratory's operations.

4.4.2.10 Publication of Fee Schedule

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

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

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

4.4.2.11.1 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 on-site 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) calendar 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.

4.4.2.11.2 *WADA* Assessment

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

As part of an announced or unannounced Laboratory on-site assessment, *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*

4.5.1 Removal of *Samples* for Further Analysis

Within the context of an investigation or Laboratory performance monitoring activity (for example, during an on-site Laboratory assessment), *WADA*, initially at its expense [12], may remove *Sample*(s) stored in a Laboratory in order to conduct Further Analysis for the purpose described in *Code* Art. 6.2. In such cases, *WADA* shall notify the Testing Authority and Results Management Authority, which shall retain ownership of the *Sample*(s) pursuant to ISTI Art. 10.1. Notwithstanding the aforementioned, *WADA* shall retain the right to request Further Analysis, at its expense, as permitted by *Code* Art. 6.5, Para. 2.

WADA may delegate an observer to monitor the removal of the *Samples*, which shall be implemented in accordance with *WADA*'s instructions. During the removal of *Samples*, *WADA* shall be responsible for maintaining proper *Sample* chain of custody documentation and the safety and integrity of the *Samples* until receipt by the other Laboratory(-ies).

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

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

4.5.2 Removal of *Samples* for Laboratory Quality Assessment

WADA may also direct the re-analysis of anonymized *Samples*, which have met the conditions described in ISL Art. 5.3.3.1, for purposes of Laboratory quality assurance and education, including the implementation of a system of transfer of *Samples* reported as Negative Findings between Laboratories [13]. In this regard, the number of *Samples* directed by *WADA* for re-analysis may vary but shall be guided by the criteria established in ISL Art. 6.2.1.1.

4.6 *WADA* Monitoring of Accreditation Status

WADA shall regularly review 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 ISL Art. 4.4.2, including satisfactory performance by a Laboratory in the EQAS and in routine Analytical Testing (see ISL Sections 6 and 7), 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 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.

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

4.6.4 Loss 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.

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.

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

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

4.6.4.1.2 Suspension of Accreditation and Analytical Testing Restriction – Disciplinary Proceedings

The LabEG may recommend to the Chairman of the *WADA* Executive Committee that a Laboratory be subject to an Analytical Testing Restriction or a Suspension of its *WADA* accreditation even if the Laboratory has not reported a False *Adverse Analytical Finding* with *Consequence*(s) for an *Athlete* or has not attained the maximum number of penalty points detailed in the ISL Points Scale Table in ISL Art. 7.3 , but where the Laboratory's other Analytical Testing failure(s) and/or other identified nonconformities (as described in ISL Art. 4.6.4.2) otherwise justifies that such action be taken to ensure the full reliability and accuracy of Analytical Testing and the accurate reporting of test results [14].

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

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

between the Laboratory and *WADA* regarding the Laboratory's accreditation status and the terms of its Analytical Testing Restriction or Suspension.

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

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

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

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

4.6.4.2 Noncompliances with the ISL

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

- Suspension, or withdrawal of ISO/IEC 17025 accreditation;
- Repeated reporting of False *Adverse Analytical Findings* and/or False Negative Findings[15]:
  - The reporting of two (2) or more independent [16] False *Adverse Analytical Finding* per EQAS round; or
  - The reporting of three (3) or more independent [16] *False Adverse Analytical Findings*, including EQAS and routine Analytical Testing, per 12-month period; or

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

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

- The reporting of three (3) or more independent [16] False Negative Findings per EQAS round; or
- The reporting of four (4) or more independent [16] False Negative Findings, including EQAS and routine Analytical Testing, per 12-month period; or
- Any combination of four (4) or more independent [16] False *Adverse Analytical Findings* and False Negative Findings, including EQAS and routine Analytical Testing, per 12-month period.

- Failure to comply with any of the requirements or standards listed in the ISL and/or Technical Documents and/or Technical Letters;
- Serious and repeated noncompliances with results reporting timelines (see ISL Arts. 5.3.5.2.5 and 5.3.5.2.7.3);
- Failure to take appropriate corrective action after an unsatisfactory performance 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 Laboratory on-site 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:
  - 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 ISL Arts. 5.2.2.6 and 5.2.2.7);
  - Significant loss or lack of experienced staff (*e.g.* Certifying Scientists) that affects, as determined by *WADA*, the Laboratory's ability to ensure the full reliability and accuracy of Analytical Testing and reporting of test results;
  - Loss of sufficient Laboratory support and resources that affects, as determined by *WADA*, the quality and/or viability of the Laboratory;
  - Failure to analyze the minimum number of *Samples* indicated in ISL Art. 4.4.2.9; or
  - Failure to cooperate in any *WADA* enquiry in relation to the activities of the Laboratory.

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.

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

- Repeated reporting of False *Adverse Analytical Findings* or repeated failure to take appropriate corrective action after the reporting of a False *Adverse Analytical Finding*;
- 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 ISL Art. 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 on-site 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(s);
- Repeated failure to take appropriate corrective action following ISL and/or Technical Document and/or Technical Letter noncompliance(s) identified from Laboratory on-site assessment(s);
- Repeated failure to analyze the minimum number of *Samples* indicated in ISL Art. 4.4.2.9;
- Continuous, serious Laboratory staff and/or management issues (*e.g.* continuous turnover of qualified staff affecting Laboratory expertise and competence, inadequate training, repeated failure to train and qualify an appropriate number of analysts as Certifying Scientists);
- Failure to cooperate with *WADA* or any relevant Testing 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 maintain administrative and operational independence as described in ISL Art. 4.4.2.4;
- 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.

4.6.4.4 Resolution Facilitation

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

Technical Letter(s) and offer the Laboratory Director an opportunity to provide further clarification to the *WADA* LabEG.

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

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

4.6.4.5 Disciplinary Proceedings

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

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

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

4.6.4.6 Notification of Decision

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

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

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

Such notice shall include:

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

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

4.6.4.7 Effective Date and Appeals

A Suspension or Analytical Testing Restriction is effective immediately upon receipt of notification of the decision.

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

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

4.6.4.8 Public Notice

WADA shall announce a change in a Laboratory's accreditation status on its website as soon as the Laboratory is notified by *WADA* of its decision. The public notice shall include the name and address of any Laboratory that has had its accreditation suspended or revoked or that has been subjected to an Analytical Testing Restriction, as well as the name of any Laboratory that has had its Suspension or Analytical Testing Restriction lifted. In cases of Laboratory Revocation, the public notice shall specify that the Laboratory shall remain under Suspension until the date when the Revocation becomes effective, as determined in ISL Art 4.6.4.7.

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

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

4.6.5 Consequences of Suspended or Revoked Accreditation or Analytical Testing Restriction

4.6.5.1 Analytical Testing Restriction

If *WADA* determines that the noncompliance(s) are limited to a class of *Prohibited Substances* or *Prohibited Methods* or to a specific Analytical Testing Procedure, *WADA* will impose an Analytical Testing Restriction for that class of *Prohibited Substance(s)* or *Prohibited Method(s)* or for the specific Analytical Testing Procedure in which the noncompliance(s) occurred.

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

If the reason for the Analytical Testing Restriction was related to the reporting of False *Adverse Analytical Finding*(s), all analyses employing the affected Analytical Testing Procedure(s) shall cease immediately.

The Laboratory shall transfer [17] the following *Samples* ("A" and "B" *Samples*) in the Laboratory's custody, which involve the analysis of the same class of *Prohibited Substances* or *Prohibited Methods* and/or the application of the affected Analytical Testing Procedure(s) subjected to the Analytical Testing Restriction, to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures (unless otherwise instructed by *WADA*):

- *Samples*, which had been previously reported as an *Adverse Analytical Finding*;
- *Samples*, which have been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Analytical Testing Restriction decision;
- *Samples* for which the "A" or "B" Confirmation Procedures had been completed, but results of the analysis had not been reported by the Analytical Testing Restriction date, or *Samples* which had been undergoing "A" or "B" Confirmation Procedures at the time of the imposition of the Analytical Testing Restriction;
- *Samples* which have been reported as an *Adverse Analytical Finding* 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 [17] to another Laboratory(-ies) for the "A" Confirmation Procedure to be performed again and for the performance of the "B" Confirmation Procedure, if applicable.

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

If the Analytical Testing Restriction has been caused by the reporting of False Negative Finding(s), and further investigation reveals that other Negative Finding(s) had been reported for *Samples* that are still stored in the Laboratory, the Laboratory shall inform the Testing Authority and *WADA*. In such cases, both the "A" and "B" containers of the relevant *Samples* shall be transferred [17] 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 *Code*-compliant *Anti-Doping Organization*. This provision does not apply when the noncompliance(s) that led to the Suspension do not affect the blood analyses for the *ABP*, as determined by *WADA*.

4.6.5.2.1 If the reason for the Suspension was related to a violation of the Code of Ethics (Annex A), all Analytical Testing in the suspended Laboratory shall cease immediately and the Laboratory shall transfer [18] all *Samples* (both the "A" and "B" *Samples*) in the Laboratory's custody to other Laboratory(-ies) chosen by the Testing Authority(-ies).

4.6.5.2.2 If the reason for the Suspension was related to the reporting of false *Adverse Analytical Finding*(s), all Analytical Testing shall cease immediately.

In addition, the Laboratory shall transfer [18] the following *Samples* ("A" and "B" *Samples*) in the Laboratory's custody to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures, unless otherwise instructed by *WADA*:

- *Samples*, which had been previously reported as an *Adverse Analytical Finding* for the same class of *Prohibited Substances* or *Prohibited Methods* when applying the same Confirmation Procedure;
- *Samples* for which Initial Testing Procedures had been completed and produced Presumptive Adverse Analytical Finding(s), but for which Confirmation Procedures had not yet been performed at the time of the Suspension;
- *Samples*, which have been opened and were undergoing analysis for the Initial Testing Procedure(s)

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

at the time of the Suspension;

- *Samples* which have been received at the Laboratory but not opened at the time of the Suspension [these *Samples* shall be kept sealed in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions until transfer [18] to another Laboratory(-ies)].
- *Samples* for which "A" or "B" Confirmation Procedures had been completed, but results of the analysis had not been reported by the Suspension date, or *Samples* which had been undergoing "A" or "B" Confirmation Procedures at the time of the Suspension;
- *Samples* which have been reported as an *Adverse Analytical Finding* based on the "A" Confirmation Procedure prior to the Suspension.

4.6.5.2.3 A Laboratory that has had its *WADA* accreditation suspended for reasons other than a violation of the Code of Ethics or the reporting of false *Adverse Analytical Findings*(s) shall take the following steps with the *Samples* in the Laboratory's custody, unless otherwise instructed by *WADA*:

- *Samples* which have been analyzed and reported as a Negative Finding, and which have either been stored in the Laboratory for a period of less than three (3) months or had been placed in long-term storage upon request by the Testing Authority or *WADA*:

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

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

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

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

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

If the reason for the Suspension was not related to the reporting of False Negative Findings and the Initial Testing Procedures have produced negative results, the *Sample*(s) shall be reported in *ADAMS* as Negative Finding(s). These *Samples* shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions until further notice by *WADA*. The Laboratory shall inform *WADA* of such actions including the provision of the *Sample* codes and the identity of the relevant Testing Authority(-ies).

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

If the reason for Suspension was not related to the reporting of False Negative Finding(s), the Laboratory shall continue to analyze the relevant *Samples* until all Initial Testing Procedures are completed. If the Initial Testing Procedures produce Negative Findings, the Laboratory shall report these findings into *ADAMS* and these *Samples* shall be kept in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until further notice by *WADA*. The Laboratory shall inform *WADA* of such actions including the provision of the *Sample* codes and the identity of the relevant Testing Authority(-ies).

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

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

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

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

- *Samples* for which "A" or "B" Confirmation Procedures had been completed, but results of analysis had not been reported by the Suspension date, or *Samples* which had been undergoing "A" or "B" Confirmation Procedures at the time of the Suspension:

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

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

These *Samples* shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions. Should a "B" Confirmation Procedure be requested during the Suspension, both "A" and "B" *Samples* shall be transferred **[18]** to another Laboratory(-ies) for the "A" Confirmation Procedure to be performed again and for the performance of the "B" Confirmation Procedure, if applicable.

4.6.5.2.4 If the Suspension concerns the analysis of blood *Samples* for the *ABP*, *Samples* collected prior to the Suspension date may be analyzed by the Laboratory [19]. The reporting of results for the relevant *Sample(s)* in *ADAMS* shall include a comment regarding the Suspension at the time of analysis so that the Testing Authority / APMU can take this information into account during the results management process.

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

4.6.5.3 Revocation

A laboratory whose *WADA* accreditation has been revoked is ineligible to perform 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 [18] of relevant *Samples* to a Laboratory(-ies).

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

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

WADA shall lift the Suspension of the Laboratory's *WADA* accreditation or lift the Analytical Testing Restriction only when the Laboratory provides satisfactory evidence, as determined by *WADA*, that appropriate steps have been taken to remedy the noncompliance(s) that resulted in the Suspension of the Laboratory's *WADA* accreditation or the imposition of the Analytical Testing Restriction, and that proper measures have been implemented to satisfactorily address the condition(s) specified, if any, for reinstatement of *WADA* accreditation.

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

[20] The laboratory shall transfer all *Samples* in its custody for which the Analytical Testing process has not been completed at the time of the Revocation. The Testing Authority may also choose to transfer additional *Samples* retained in the laboratory in accordance with ISL Arts. 5.3.2.1. or 5.3.2.2, or other *Samples* for which it is the owner pursuant to Art. 10.1 of the ISTI and that have been analyzed and are in long-term storage at the time of the Revocation of the laboratory's *WADA* accreditation. In addition, *WADA* may identify and request that *Samples* be transferred to another Laboratory(-ies).

4.6.6.1 Extension of Suspension or Analytical Testing Restriction

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

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

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

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

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

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

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

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

4.6.6.2 Revoked Accreditation

If a laboratory whose *WADA* accreditation has been revoked wishes to seek a new *WADA* accreditation, it must apply for *WADA* accreditation as a new laboratory in accordance with ISL Art. 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 ISL Arts. 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 ISL Arts. 4.6.5.2 (temporary closure) or 4.6.5.3 (permanent closure). In addition, if the Laboratory decides to cease its operations on a permanent basis, the Laboratory shall assist the relevant Testing Authority(-ies) with the transfer of relevant *Sample* data and records to the Laboratory(-ies) that have been selected to receive the *Samples*.

4.7 Accreditation Requirements for Major Events

Major Event Organizations should give preference to use existing facilities of a Laboratory for the analysis of *Samples*.

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

In addition, the Laboratory operations necessary for a Major Event may be such that the existing Laboratory facilities are not adequate. This may require the expansion of existing facilities, re-location of the Laboratory to a new permanent facility, the addition of personnel, and/or the acquisition of additional equipment. The 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 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. The Laboratory shall be required to report on staffing and equipment issues as required by *WADA*.

4.7.1 Major Event Analytical Testing in the Laboratory Facilities

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

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

4.7.1.1 Participation in *WADA* Assessment(s)

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

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

4.7.1.2 Participation in the *WADA* EQAS

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

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

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

4.7.1.3 Completing a Pre-*Event* Report on Facilities and Staff

4.7.1.3.1 The Laboratory shall inform *WADA* of all senior personnel temporarily working in the Laboratory for the Major Event.

4.7.1.3.2 The Laboratory Director shall ensure that these personnel are adequately trained in the methods, policies, and procedures of the Laboratory. Particular emphasis should be given to the Code of Ethics and the confidentiality of the results management process. Adequate documentation of training of these temporary employees shall be maintained by the Laboratory.

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

- A valid signed contract between the Laboratory and the responsible Testing Authority / *Major Event Organization* including a Test Distribution Plan detailing the *Sample* collection schedule, number of urine and blood *Samples* and requests for specific analyses (*e.g.* agents affecting erythropoiesis);
- 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 training plan with timelines for new staff, including temporary staff and invited scientists;
- A list of instrumental resources and equipment including identification of ownership;
- A summary of the results management process including criteria for determining analytical results (*Adverse Analytical Findings*, *Atypical Findings*, etc.); and
- 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 should be immediately reported to *WADA*.

4.7.1.3.4 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.

4.7.2 Major Event Analytical Testing in "Satellite" Laboratory Facilities

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

4.7.2.1 Participating in an initial *WADA* / Accreditation Body Assessments

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

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

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

4.7.2.4 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".

4.7.2.5 Participating in *WADA* Accreditation Assessment(s)

WADA shall perform on-site assessment(s) or document audit(s) of the "satellite facility". Expenses related to such visit(s) shall be at the Laboratory's expense. These assessment(s) may include analysis of a set of EQAS samples. Particular emphasis will be placed on involvement of new staff members to assess their competence.

4.7.2.6 Professional Liability Insurance Coverage

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

4.7.2.7 Obtaining a Temporary and Limited *WADA* Accreditation Certificate

The Laboratory's "satellite facility" shall obtain a Temporary and Limited *WADA* Accreditation Certificate for the Major Event.

Based on the documentation provided, *WADA* reserves the right to make a decision regarding accreditation of the Laboratory "satellite facility". In the event that the accreditation is awarded, *WADA*

shall issue 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.

4.7.3 Monitoring and Assessment during a Major Event

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

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

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

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

4.8 Process for approval of Laboratories for the *ABP*

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

4.8.1 Applicant Laboratory for *WADA* approval for the *ABP*

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

4.8.1.1 Expression of Interest

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

4.8.1.2 Submit Initial Application Form

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

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

- The existence of a National Anti-Doping Program conducted by a *National Anti-Doping Organization* and/or a *Regional Anti-Doping Organization* which is compliant with the *Code* and the *International 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.

4.8.1.3 Provision of Letter(s) of Support

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

4.8.2 Candidate Laboratory for *WADA* approval for the *ABP*

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

4.8.2.1 Description of the Candidate Laboratory

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

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

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

4.8.2.2 Laboratory Independence and Impartiality

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

- Administrative independence requires that the laboratory is a separate legal entity without any administrative links to an *Anti-Doping Organization* or other sport or political organizations;
- Operational independence requires that the laboratory shall manage its own affairs without hindrance, interference or direction from any *Anti-Doping Organization*, sport organizations or any *Person*.

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

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

4.8.2.4 Obtaining ISO/IEC 17025 or ISO 15189 Accreditation

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

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

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

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

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

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

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

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

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

4.8.2.7 Professional Liability Insurance Coverage

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

4.8.3 Granting of *WADA* Approval for the *ABP*

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

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

4.8.3.1 Issuing and Publishing of *WADA* Approval Certificate for the *ABP*

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

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

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

- Analysis of *ABP* blood *Samples* from Testing Authorities, which are *Code*-compliant *Anti-Doping Organizations*, as determined by *WADA*;
- Satisfactory performance, as determined by *WADA*, in a *WADA* EQAS or similar *WADA*-approved quality assurance program for the analysis of *ABP* blood *Markers* and during routine Analytical Testing of *ABP* blood *Samples;*
- Maintenance of a valid ISO accreditation (ISO/IEC 17025 or ISO 15189);
- Availability of analytical instrumentation, which is compliant with the requirements of the hematological module of the *ABP*, as determined by *WADA*;
- Implementation of Analytical Testing Procedures for the measurement of individual *Athlete* blood *Markers*, which are in compliance with the TD BAR;
- Compliance with relevant *WADA* documents, including the relevant articles of the ISL Section 5 relevant to the analysis of blood *Samples*;
- Documented compliance with the Code of Ethics (ISL Annex A);
- Maintenance of Professional Liability Insurance Coverage;

- Implementation of Laboratory Internal Chain of Custody procedures, which are compliant with the Technical Document on Laboratory Documentation Packages (TD LDOC);
- Production of Blood *ABP* Laboratory Documentation Packages or Blood *ABP* Laboratory Certificates of Analysis in compliance with the TD LDOC;
- Cooperation in support of the administrative and legal processes instigated when anti-doping rule violations are issued and managed by *Anti-Doping Organizations*.

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

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

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

5.1 Introduction and Scope

This section of the 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. The application focuses on the specific parts of the processes that are critical with regard to the quality of the Laboratory's performance as a *WADA*-accredited laboratory (*i.e.* a Laboratory) or WADA-Approved Laboratory for the ABP and are therefore significant in the evaluation and accreditation process.

This section introduces the specific performance standards for a Laboratory or WADA-Approved Laboratory for the ABP, 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.

5.2.2 Laboratory Personnel

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

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

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

5.2.2.4 Laboratory Director

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

The Laboratory Director qualifications shall include:

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

Any personnel changes to the position of Laboratory Director shall be communicated to *WADA* no later than one (1) month prior to the scheduled date the Laboratory Director vacates his/her position. A succession plan shall be forwarded to *WADA*. *WADA* reserves the right to review the credentials of such appointment and either approve it or reject it in accordance with the above qualifications.

5.2.2.5 Laboratory Quality Manager

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

The Laboratory Quality Manager qualifications shall include:

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

5.2.2.6 Laboratory Certifying Scientists

The Laboratory shall have qualified personnel to serve as Certifying Scientists to review all pertinent analytical data, Analytical Method validation results, quality control results, Laboratory Documentation Packages, and to attest to the validity of the Laboratory's test results.

The qualifications of Certifying Scientists shall include:

- At least a Bachelor's Degree (or similar) in one of the natural sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area. In the absence of a bachelor's degree, documented experience of five (5) years or more in a Laboratory as

senior scientist (*e.g.* supervisor, section head) may be considered equivalent to a Bachelor's degree for this position;

- Appropriate training and experience of three (3) years or more, as well as theoretical knowledge and technical competence in the analysis and interpretation of results for chemical or biological materials, including the classes of substances and methods used in doping;
- Knowledge of relevant *WADA* Technical Documents, Technical Letters, Laboratory Guidelines and other technical standards;
- Experience in the use of relevant analytical techniques such as chromatography, immunoassays, electrophoresis or mass spectrometry;
- Adequate training in the Laboratory's Management System and thorough understanding of its application into Laboratory processes.

5.2.2.7 Laboratory Supervisory Personnel

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

The qualifications for a Laboratory Supervisor shall include:

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

5.2.3 Laboratory facility and Environmental Conditions

5.2.3.1 Environmental Control

5.2.3.1.1 Maintaining Appropriate Electrical Services

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

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

5.2.3.1.3 The storage and handling of controlled substances shall comply with applicable national legislation.

5.2.3.2 Security of the Facility, Equipment and Systems

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

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

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

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

- Reception Zone: An initial point of control beyond which unauthorized individuals shall not be permitted.

  The Laboratory shall have a system to register visitors and authorized individuals to the Laboratory. They shall be supplied with an identification badge while in the Laboratory facilities.

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

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

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

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

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

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

5.2.3.3 Confidentiality of data, information and operations

- The Laboratory should implement a clean desk policy and either file securely any confidential or sensitive information or properly destroy it before disposal. Laboratory staff shall be trained on how to

[21] This refers to "A" and "B" *Samples* stored in *Sample* collection containers (urine collection bottles, blood collection tubes) and should not be confused with access to Aliquots, which should be accessible to analysts for the performance of Analytical Testing Procedures.

comply with a clean desk policy, on how to ensure confidentiality of information and operations, as well as on the risks of corruption attempts by third parties.

- Laboratory staff shall be trained to protect their personal access badge during and out of working hours.
- In order to minimize any attempts of fraud or counterfeit, the Laboratory should implement a policy to ensure that discarded urine and blood *Sample* containers, as well as the seals and rings, cannot be collected by unauthorized staff or recovered after disposal (for example, bottles should be destroyed, or trash containers should be properly sealed).

5.2.3.4 Control of Data and Computer Security

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

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

5.2.3.4.3 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 as well as information and data exchange capabilities (*e.g.* with Laboratory instruments and *ADAMS*). The system may also feature workflow management, data tracking support, *Sample* and Aliquot Laboratory Internal Chain of Custody, control of stocks of Reference Materials, etc., which can also be addressed with proper documentation.

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

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

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

5.2.3.5 Laboratory Equipment

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

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

5.2.3.5.3 General Laboratory equipment (fume hoods, centrifuges, evaporators, etc.) that is not used for analytical measurements should be maintained by visual examination, safety checks, performance verification and cleaning as necessary. Calibrations are only required where the setting can significantly change the test result. A maintenance schedule, at least in accordance with the manufacturer's recommendations or local regulations, if available, shall be established for general Laboratory equipment that is used in Analytical Testing Procedure(s).

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

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

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

5.2.3.6 Relocation of Laboratory Facilities

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

- Description of the circumstances for moving Laboratory operations into a new space and anticipated effect on capabilities;
- Relocation date(s) including date of closing of existing facility operations and date of opening of future facility operations;
- 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 facility required when made available by the Accreditation Body);
- New Laboratory contact information and coordinates;
- Assessment of the effect of the Laboratory relocation on client operations.

5.3 Process Requirements

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

5.3.1 Reception, Registration and Handling of *Samples*

5.3.1.1 The Laboratory may receive *Samples*, which have been collected, sealed and transported to the Laboratory according to the *WADA's* International Standard for Testing and Investigations (ISTI).

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

5.3.1.3 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).

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

5.3.1.5 *Samples* with irregularities

5.3.1.5.1 With the exception of the situation when a large number of *Samples* are received for long-term storage only (*e.g.* from a *Major Event Organizer*), as described in ISL Art. 5.3.2.3, the Laboratory shall observe and document conditions that exist at the time of *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 test menu, is not provided, *e.g.* missing or incomplete Doping Control Form (DCF);
- *Sample* identification is questionable. For example, the number on the *Sample* container does not match the *Sample* identification number on the DCF;
- *Athlete* information is visible on the Laboratory copy of the DCF or any other document transferred to the Laboratory;
- *Sample* identification numbers are different between the "A" and the "B" *Sample* containers of the same *Sample*;
- *Tampering* or adulteration of the *Sample* is evident;
- *Sample* is not sealed with tamper-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* [22].

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

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

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

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

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

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

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

5.3.1.6 *Sample* Splitting Procedure

In cases when either the "A" or "B" *Sample* is not suitable for the performance of the analyses (*e.g.* there is insufficient *Sample* volume; the *Sample* container has not been properly sealed and is leaking or has been broken; the *Sample*'s integrity has been compromised in any way; the *Sample* is heavily contaminated), the Laboratory, in consultation with the Testing Authority, should consider splitting the other *Sample* container ("A" or "B", as applicable), provided that it is properly sealed. This process may be applied repeatedly, if necessary.

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

The process of opening and splitting the *Sample* and resealing of the remaining second fraction shall be conducted in accordance with ISL Arts. 5.3.4.5.4.8.6 and 5.3.4.5.4.8.9 as for a customary "B" *Sample* opening, including an attempt to notify the *Athlete* that the opening of the *Sample* to be split will occur on a specified date and time and advising the *Athlete* of the opportunity to observe the process in person and/or through a representative [23]. When the *Athlete* and/or his/her representative does not attend the opening and splitting of the *Sample*, the procedure shall be done in the presence of an Independent Witness that is assigned by the Laboratory.

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

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

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

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

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

- The Laboratory may conduct analyses on the additional collected *Samples*, if deemed necessary, with the agreement of the Testing Authority;
- The Laboratory may 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;
- *Samples* not subject to analysis shall be reported as "Not Analyzed" in *ADAMS*, and the reason(s) for not analyzing the *Sample* shall be specified (*e.g.* additional *Sample* from a single Sample Collection Session).

5.3.2 Storage of *Samples* [24]

5.3.2.1 Storage of Urine *Samples*

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

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

5.3.2.1.3 All urine 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.*

5.3.2.1.4 Urine *Sample*(s) without an *Adverse Analytical Finding* or *Atypical Finding*

The Laboratory shall retain the "A" and "B" urine *Sample*(s) without an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of three (3) months after reporting the final analytical result in *ADAMS*, or

[24] This refers to "A" and "B" *Samples* stored in *Sample* collection containers (urine collection bottles, blood collection tubes) and should not be confused with access to Aliquots, which should be accessible to analysts for the performance of Analytical Testing Procedures.

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* [25].

5.3.2.1.5 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* [25].

5.3.2.1.6 Urine *Sample*(s) with an *Adverse Analytical Finding* or *Atypical Finding*

The Laboratory shall retain the "A" and "B" urine *Sample*(s) with an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of six (6) months after reporting the final analytical result (for the "A" or the "B" *Sample*, as applicable) in *ADAMS* [26], or for a longer period as informed to the Laboratory, in writing, by the relevant Testing Authority, Results Management Authority or *WADA* [25].

5.3.2.1.7 Urine *Samples* under challenge, dispute or investigation

If the Laboratory has been informed by the Testing Authority, the Results Management Authority or *WADA* (in writing and within the applicable storage period as defined in ISL Arts. 5.3.2.1.4 to 5.3.2.1.6) that the analysis of a urine *Sample* is challenged, disputed or under investigation, the Laboratory shall retain both the "A" and "B" *Samples* until further notice by the Testing Authority, the Results Management Authority or *WADA*, as applicable [25].

5.3.2.2 Storage of Blood *Samples*

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

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

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

The "A" *Sample* serum or plasma fraction (contained in the "A" *Sample* collection tube) and/or the "A" *Sample* serum or plasma Aliquots may be stored refrigerated for a maximum of 24 hours (but not surpassing the maximum allowed time from *Sample* collection established in the applicable Technical

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

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

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

Document, Technical Letter or Laboratory Guidelines) or frozen until analysis. In all circumstances, the Laboratory shall take the appropriate steps to maintain the integrity of the *Sample*.

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

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

All serum or plasma 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*.

5.3.2.2.1.1 Serum/plasma "A" and "B" *Samples* without an *Adverse Analytical Finding* or *Atypical Finding*

The Laboratory shall retain the serum/plasma "A" and "B" *Samples* without an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of three (3) months after reporting the final analytical result in *ADAMS*, or for a maximum of ten (10) years after the *Sample* collection date, if the long-term storage of the *Sample*(s) has been requested by the relevant Testing Authority or *WADA* [25].

5.3.2.2.1.2 Serum/plasma *Samples* with irregularities

The Laboratory shall retain the serum/plasma *Samples* with irregularities for a minimum of three (3) months after reporting the final analytical result in *ADAMS*, or for a longer period as determined by the Testing Authority, Results Management Authority or *WADA* [25].

5.3.2.2.1.3 Plasma/serum "A" and "B" *Sample(s)* with an *Adverse Analytical Finding* or *Atypical Finding*

The Laboratory shall retain "A" and "B" plasma/serum *Sample(s)* with an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of six (6) months after reporting the final analytical result (for the "A" or the "B" *Sample*, as applicable) in *ADAMS* [26] or for a longer period as informed to the Laboratory, in writing, by the relevant Testing Authority, Results Management Authority or *WADA* [25].

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

If the Laboratory has been informed by the Testing Authority, the Results Management Authority or *WADA* (in writing and within the applicable storage period as defined in ISL Arts. 5.3.2.2.1.1 to 5.3.2.2.1.3) that the analysis of a serum/plasma *Sample* is challenged, disputed or under investigation, the Laboratory shall retain both the "A" and "B" *Samples* until further notice by the Testing Authority the Results Management Authority or *WADA*, as applicable [25].

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

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

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

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

5.3.2.3 Long-term Storage of *Samples*

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

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

5.3.2.3.3 The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to a stored *Sample* for the duration of *Sample* storage, either as hard-copy or in digital format. In addition, the Laboratory may retain *Sample* analytical data which would allow retrospective analysis of such data, for example, for the purpose of identifying signals for novel *Metabolite*(s) of *Prohibited Substances*(s) or *Marker*(s) of *Prohibited Substances*(s) or *Prohibited Method*(s) (*e.g.* full-scan mass spectrometry data) as provided for in ISL Art. 5.3.4.5.5.9.

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

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

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

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

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

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

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

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

5.3.3 Use, Transfer or Disposal of *Samples*

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

- Dispose of the *Sample(*s) [29];
- If consent has been obtained from the *Athlete,* retain the *Samples* for research purposes. *Samples* used for research purposes shall have any means of identification removed or the *Sample* shall be transferred into an anonymous container such that the contents cannot be traced back to a particular *Athlete*. Research *Samples* may be transferred to other Laboratories or third parties (*e.g.* other research groups);
- If consent has not been obtained from the *Athlete*, retain the anonymized *Samples* for quality assurance, quality improvement of existing Test Methods, development or evaluation of new 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, which are not considered as research. As such, these *Samples* may be used by the Laboratory or transferred to other Laboratories or to third parties for these purposes.

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

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

5.3.3.2 The Laboratory shall maintain SOP(s) pertaining to the retention, use for research or quality assurance, transfer and disposal of *Samples* and Aliquots.

5.3.4 *Sample* Analysis

5.3.4.1 Aliquoting for Analysis

5.3.4.1.1 It is recommended that the Laboratory assigns specific staff member(s) to *Sample* aliquoting, and that the process of aliquoting is performed in a specifically designated area (see ISL Art. 5.2.3.2.4).

5.3.4.1.2 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.

For urine *Samples*, the Laboratory shall obtain, following proper homogenization of the *Sample*, an initial Aliquot containing enough *Sample* volume for all analytical procedures (all Initial Testing Procedures or all intended Confirmation Procedures, as applicable), by decanting the Aliquot from the urine *Sample* container into a secondary container (*e.g.* a Falcon tube). Procedure-specific Aliquot(s) shall then be taken from the secondary container.

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

5.3.4.1.3 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 Endogenous Anabolic Androgenic Steroids Measuring and Reporting, TD EAAS).

5.3.4.2 Selection of Analytical Testing Procedures

Standard methods are generally not available for *Doping Control* analyses. The Laboratory shall select, validate and document Analytical Testing Procedures, which are Fit-for-Purpose for the analysis of representative target Analytes of *Prohibited Substances* and *Prohibited Methods*.

5.3.4.3 Measurement Traceability

5.3.4.3.1 Reference Materials

When available, Reference Materials of substances traceable to a national standard or certified by a body of recognized status (*e.g.* USP, BP, Ph.Eur. WHO) or a Reference Material producer accredited to ISO Guide 34: 2009[*] or ISO 17034 should be used.

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

[*] until 30 November 2019.

5.3.4.3.2 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.

5.3.4.4 Validation of Analytical Testing Procedures [30, 31]

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

5.3.4.4.1 Validation of Analytical Testing Procedures for Non-Threshold Substances

The Laboratory shall develop, as part of the method validation process, appropriate standard solutions for detection and/or identification and estimation of the concentration of Non-Threshold Substances using Reference Materials. In the absence of suitable Reference Materials, Reference Collections may be used for detection and identification.

5.3.4.4.1.1 Validation of Initial Testing Procedures for Non-Threshold Substances

- The Laboratory shall validate the Selectivity, reproducibility 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 chromatography-mass spectrometry based Analytical Methods, the Initial Testing Procedure shall allow the detection of each Non-Threshold Substance or its representative *Metabolite*(s) or *Marker*(s) at 50% or less of the Minimum Required Performance Levels (MRPL) (see the Technical Document on Minimum Required Performance Levels, TD MRPL);

- If there is no available Reference Material, an estimate of the detection capability of the Initial Testing Procedure (*i.e.* the LOD) for the Non-Threshold Substance or its representative *Metabolite*(s) or *Marker*(s) may be provided by assessing a representative substance from the same class of *Prohibited Substances* with a similar chemical structure.

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

[31] The Laboratory shall define and document the conditions that would trigger the revalidation of an Analytical Testing Procedure (*e.g.* change of internal standard, modified extraction procedure or chromatographic methodology, change in detection technique) or a partial re-assessment of the validation process (*e.g.* replacement or upgrade of instrument, addition of new Analyte to the Analytical Method).

5.3.4.4.1.2 Validation of Confirmation Procedures for Non-Threshold Substances

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

- Selectivity: The ability of the Confirmation Procedure to detect and identify only the substance of interest, taking into account interference(s) from the matrix or from other substance(s) present in the *Sample*. Selectivity shall be determined and documented from the analysis of an adequate number of representative samples prepared in the matrix of *Sample* analysis, in compliance with the Technical Document on Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for *Doping Control* Purposes (TD IDCR) or other applicable Technical Document, Technical Letter or Laboratory Guidelines. The Confirmation Procedure shall be able to discriminate between compounds of closely related structures.
- Limit of Identification (LOI): When the analyses of Non-Threshold Substances are based on chromatographic-mass spectrometric techniques, the Laboratory shall determine the lowest concentration at which each Non-Threshold Substance or its representative *Metabolite*(s) or *Marker*(s), for which a Reference Material is available, is consistently identified (in compliance with the TD IDCR or other applicable Technical Document, Technical Letter or Laboratory Guidelines). The LOI shall not exceed the applicable MRPL [32].
- Robustness: The Confirmation Procedure shall be demonstrated to produce similar results with respect to minor variations in analytical conditions, which may affect the results of the analysis. Those conditions that are critical to ensuring reproducible results shall be considered.
- Carryover: The conditions required to eliminate carryover of the substance of interest from *Sample* to *Sample* during processing or instrumental analysis [33].

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[32] The TD MRPL requirement that the LOD, estimated during method validation, shall be equal to or less than 50% of the MRPL, is applicable to the Initial Testing Procedures and not to the Confirmation Procedures. This ensures the detection of the Non-Threshold Substance (or its representative *Metabolite* or characteristic *Marker*, as applicable) at the MRPL at all times, which then triggers the subsequent performance of a Confirmation Procedure.

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

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

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

5.3.4.4.2 Validation of Analytical Testing Procedures for Threshold Substances

As part of the validation process for chromatography-mass spectrometric Analytical Methods applied to the analysis of Threshold Substances, the Laboratory shall develop acceptable standard solutions for identification of Threshold Substances using Reference Materials. For Confirmation Procedures, Certified Reference Materials should be used for quantification, if available.

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

5.3.4.4.2.1 Validation of Initial Testing Procedures for Threshold Substances

- The Laboratory shall validate Initial Testing Procedures that are Fit-for-Purpose, in accordance with relevant *WADA* Technical Document(s), Technical Letter(s) or Laboratory Guidelines;
- For chromatography-mass spectrometry based Initial Testing Procedures, the Laboratory shall validate the Selectivity, LOD and linear range from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis [34];
- The Laboratory should determine the cut-off levels, based on the estimated concentrations of Threshold Substances, which will require quantitative Confirmation Procedure(s) [35]. The Laboratory shall validate the reproducibility of determinations at the cut-off level;
- The estimation of Measurement Uncertainty (MU) is not required during the validation of Initial Testing Procedures [34].

5.3.4.4.2.2 Validation of Confirmation Procedures for Threshold Substances

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

- Selectivity, LOI, Robustness, Carryover (see ISL Art. 5.3.4.4.1.2).
- Limit of quantification (LOQ): The Laboratory shall demonstrate that a quantitative Confirmation Procedure has an established LOQ of no more than 50% of the Threshold value or in accordance with the LOQ values required in relevant Technical Document(s) or Laboratory Guidelines.
- Dynamic/Linear Range: The range of the quantitative Confirmation Procedure shall be documented from at least 50% to 200% of the Threshold value.
- Repeatability (s_r): The quantitative Confirmation Procedure shall allow for the reliable repetition of the results over a short time, using a single operator, item of equipment, etc. Repeatability at the

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

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

Threshold shall be determined.

- Intermediate Precision (s_w): The quantitative Confirmation Procedure shall allow for the reliable repetition of the results at different times and with different operators and instruments, if applicable, performing the assay. Intermediate Precision at the Threshold shall be determined.

- Bias (*b*): The Bias of the measurement procedure shall be evaluated either using Certified Reference Materials or traceable Reference Materials, if available, or from comparison with a reference method or with the consensus values obtained from an inter-Laboratory comparison study or EQAS participation. Bias at the levels close to the Threshold shall be determined.

- Measurement Uncertainty (MU): The MU associated with the results obtained with the quantitative Confirmation Procedure shall be estimated in accordance with the Technical Document on Decision Limits for the Confirmatory Quantification of Threshold Substances (TD DL) or other applicable Technical Document, Technical Letter or Laboratory Guidelines. At least, MU at levels close to the Threshold shall be determined.

5.3.4.4.2.3 Estimation of Measurement Uncertainty for Quantitative Analyses

- MU of quantitative results, particularly at or close to the Threshold, shall be addressed during the validation of the quantitative Confirmation Procedure;

- MU is further addressed in the TD DL and other relevant Technical Document(s) (*e.g.* TD GH) and Laboratory Guidelines;

- Confirmation Procedure method validation data (including the estimation of MU) is evaluated during the assessment process for inclusion of the quantitative Confirmation Procedure within the Laboratory's Scope of ISO/IEC 17025 Accreditation. Therefore, for those Confirmation Procedures that are included within the Laboratory's Scope of ISO/IEC 17025 Accreditation, the Laboratory is not required to produce method validation data or other evidence of method validation in any legal proceeding.

5.3.4.5 Application of Analytical Testing Procedures

5.3.4.5.1 At minimum, all Laboratories are required to implement all mandatory Analytical Testing Procedures [36], 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

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

Prohibited Substances or *Prohibited Methods*.

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

However, if the Analytical Testing Procedure has not been included yet in the Laboratory's Scope of ISO/IEC 17025 Accreditation, the Laboratory shall validate the procedure in compliance with the ISL and the applicable Technical Document(s), Technical Letter(s) or Laboratory Guidelines prior to its application to the analysis of *Samples*. In such cases, the Laboratory may be required to provide Analytical Method validation documentation or EQAS performance data in support of an *Adverse Analytical Finding* (see ISL Art. 4.4.2.2).

5.3.4.5.2 Laboratories may apply additional Analytical Testing Procedures to analyze *Samples* for *Prohibited Substances* or *Prohibited Methods* not included in the standard Analytical Testing menu or in the Technical Document for Sport Specific Analysis (TD SSA), if the additional work is conducted at the Laboratory's expense and does not significantly affect the possibility to submit the *Sample*, as identified by the Testing Authority or *WADA*, to Further Analysis. Results from any such analysis shall be reported in *ADAMS* and have the same validity as any other test result [37].

5.3.4.5.3 Application of Initial Testing Procedures

5.3.4.5.3.1 The Initial Testing Procedure(s) applied shall be recorded, as part of the *Sample* (or *Sample* batch) record, each time it is conducted.

5.3.4.5.3.2 The Initial Testing Procedure(s) shall be performed on Aliquot(s) taken from the container identified as the "A" *Sample* [38].

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

5.3.4.5.3.4 The objective of the Initial Testing Procedure is to obtain information about the potential presence of *Prohibited Substance*(s) or *Metabolite*(s) of *Prohibited Substance*(s), or *Marker*(s) of the *Use* of a *Prohibited Substance* or *Prohibited Method.*

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

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

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

5.3.4.5.3.6 All batches undergoing an Initial Testing Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis [39].

5.3.4.5.3.7 The Initial Testing Procedures for Non-Threshold Substances shall include appropriate controls of representative substance(s) at or below the MRPL.

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

5.3.4.5.3.9 Results from Initial Testing Procedures are not required to consider the associated MU [39].

5.3.4.5.3.10 The Laboratory shall establish criteria, based on its method validation and in accordance with its SOP, to evaluate results from an Initial Testing Procedure as a Presumptive Adverse Analytical Finding, which would trigger confirmation analyses. However, a Presumptive Adverse Analytical Finding from an Initial Testing Procedure is not a necessary condition to perform Confirmation Procedures (*e.g.* GC/C/IRMS analysis may be performed upon request from the Testing Authority or *WADA*).

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

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

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

5.3.4.5.4 Application of Confirmation Procedures

5.3.4.5.4.1 The Confirmation Procedure(s) shall be recorded, as part of the *Sample* (or *Sample* batch) record, each time it is conducted.

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

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

5.3.4.5.4.4 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

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

Confirmation Procedure should incorporate, when possible and adequate, a different *Sample* extraction protocol and/or a different analytical methodology [40].

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

5.3.4.5.4.6 Confirmation Procedure Methods

- Mass spectrometry (MS) coupled to chromatographic separation (*e.g.* gas or liquid chromatography) is the analytical technique of choice for confirmation of most *Prohibited Substances*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker*(s) of the *Use* of a *Prohibited Substance* or *Prohibited Method*. These are acceptable methods for both the Initial Testing Procedure and the Confirmation Procedure if Fit-for-Purpose;
- 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, the Fitness-for-Purpose of any such purification or separation method;
- In 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.

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

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

5.3.4.5.4.7 "A" *Sample* Confirmation Procedure

5.3.4.5.4.7.1 The "A" Confirmation Procedure shall be performed using new Aliquot(s) taken from the container identified as the "A" *Sample* [41]. At this point, the link between the *Sample* external code as shown in the *Sample* container and the Laboratory internal *Sample* code shall be verified.

5.3.4.5.4.7.2 If the presence of more than one (1) *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker*(s) of the *Use* of a *Prohibited Substance* or *Prohibited Method* is 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 volume available in the "B" *Sample*).

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

5.3.4.5.4.7.3 When there is a Presumptive Adverse Analytical Finding for Amfetamine, Methylphenidate, Beta-2 Agonists, Diuretics, Glucocorticoids or Beta-blockers, or for any other *Prohibited Substance* or *Prohibited Method* whose *Use* has been declared by the *Athlete* on the DCF, the Laboratory may contact the Testing Authority to enquire whether an approved Therapeutic Use Exemption (*TUE*) exists for the *Prohibited Substance(s)* detected [42, 43]. When possible, the Laboratory should provide the concentration of the Analyte(s) as estimated during the Initial Testing Procedure. Any such contact with the Testing Authority shall be confirmed in writing (for further guidance, refer to the Laboratory Guidelines on *TUE* enquiries).

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

No final Test Report incorporating a Presumptive Adverse Analytical Finding shall be issued [44]. In cases

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

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

[43] However, unless there is a prior agreement between the Testing Authority and the Laboratory, contacting the Testing Authority in such cases does not constitute an absolute requirement for the Laboratory. The Laboratory may proceed to confirm the Presumptive Adverse Analytical Finding for Amfetamine, Methylphenidate, Beta-2 Agonists, Glucocorticoids, Diuretics, Beta-blockers or a declared *Prohibited Substance* or *Prohibited Method* and report an *Adverse Analytical Finding* in *ADAMS* according to the confirmation results obtained. In such cases, the existence or absence of an approved *TUE* shall be taken into consideration during the results management process.

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

when the Testing Authority confirms to the Laboratory the existence of an approved *TUE* for the *Prohibited Substance*, the Laboratory shall report the result as a Negative Finding as instructed by the Testing Authority.

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

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

5.3.4.5.4.7.5 "A" *Sample* Confirmation Procedure for Non-Threshold Substances

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

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

5.3.4.5.4.7.6 "A" *Sample* Confirmation Procedure for Threshold Substances

For Threshold Substances, *Adverse Analytical Finding* or *Atypical Finding* decisions for the "A" *Sample* results shall be based on the confirmed identification (in accordance with the TD IDCR, applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance and/or its *Metabolite(s)* or *Marker(s)* and their quantitative determination in the *Sample* at a level exceeding the value of the relevant Decision Limit, which is specified in the TD DL or other applicable Technical Document(s) (*e.g.* TD GH) or Laboratory Guidelines. By determining that the test result exceeds the Decision Limit, the quantitative Confirmation Procedure establishes that the Threshold Substance or its *Metabolite(s)* or *Marker(s)* is present in the *Sample* at a level greater than the Threshold, with a statistical confidence of at least 95% (for more information, refer to the TD DL).

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 [45]. If there is not enough *Sample* volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

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

For endogenous Threshold Substances, *Markers* of the "steroid profile", or any other *Prohibited Substance* that may be produced endogenously at low levels, *Adverse Analytical Finding* decisions for the "A" *Sample* results may also be based on the application of any Fit-for-Purpose Confirmation Procedure that establishes the exogenous origin of the *Prohibited Substance* or its *Metabolite*(s) or *Marker*(s) (*e.g.* GC/C/IRMS). *Atypical Findings* may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the *Prohibited Substance* or its *Metabolite*(s) or *Marker*(s).

For some exogenous Threshold Substances, which are identified as such in the *Prohibited List* and the TD DL, *Adverse Analytical Finding* decisions for the "A" *Sample* do not require a quantification procedure if detected in the presence of any *Prohibited Substance* classified under Section S5. "Diuretics and Masking Agents" of the *Prohibited List*. In such cases, the identification (in accordance to the TD IDCR) of the Threshold Substance and/or its *Metabolite*(s) in the *Sample* is sufficient to conclude an *Adverse Analytical Finding*.

5.3.4.5.4.8 "B" *Sample* Confirmation

5.3.4.5.4.8.1 A "B" Confirmation Procedure shall be performed using Aliquot(s) taken from the container defined as the "B" *Sample* [46].

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

5.3.4.5.4.8.3 It is the responsibility of the Testing Authority and/or Results Management Authority, as applicable, to inform the Laboratory, in writing, whether the *Athlete* has waived his/her right to the analysis of the "B" *Sample* and, therefore, whether or not the "B" Confirmation Procedure will be performed. This information shall be provided within the minimum *Sample* storage requirements established in ISL Arts. 5.3.2.1 and 5.3.2.2.

The Testing Authority and/or Results Management Authority, at its discretion, may decide to proceed with the "B" *Sample* analysis, and inform the Laboratory accordingly, even when the *Athlete* waives his/her right to the "B" *Sample* analysis or if the *Athlete* does not respond to requests on his/her decision to perform the "B" *Sample* analysis.

5.3.4.5.4.8.4 The Testing Authority or Results Management Authority should contact the Laboratory to provide information and/or instructions in writing regarding the "B" *Sample* analysis within ten (10) working days following the notification of an "A" *Sample Adverse Analytical Finding* by the Laboratory.

5.3.4.5.4.8.5 The "B" *Sample* confirmation should be performed as soon as possible, and no later than three (3) months, following the reporting of the "A" *Sample Adverse Analytical Finding*.

5.3.4.5.4.8.6 The following non-Laboratory *Persons* shall be authorized to attend the "B" *Sample*

[46] In cases when the "B" *Sample* cannot be used for Analytical Testing the unopened, sealed "A" *Sample* may be split (see ISL Article 5.3.1.6) and the "B" Confirmation Procedure(s), if needed, may be performed on an Aliquot taken from the split, resealed "A" *Sample* fraction designated as the "B" *Sample*.

Confirmation Procedure:

- The *Athlete* and/or one representative [47] of the *Athlete* or, in the absence of the *Athlete* and/or representative, an Independent Witness [48];
- A translator (if applicable);
- A representative of the Testing Authority or the Results Management Authority (if requested by the Testing Authority or the Results Management Authority, respectively);
- A representative of *WADA* or of *WADA*'s Independent Observers (IO) Team for Major Events (if requested by *WADA* or the IO team, respectively);
- A representative of the *National Olympic Committee* and/or National Sport Federation and/or International Federation, as applicable, may also attend the "B" *Sample* opening procedure, upon request and with prior approval by the Laboratory Director.

If the *Athlete* declines to be present in person and/or through a representative, or does not indicate whether he or she requests the "B" *Sample* analysis, or if the *Athlete* will not attend (in person or and/or through a representative) once a date and time for the analysis has been proposed or if the *Athlete* or the *Athlete's* representative 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 and appoint an Independent Witness to verify that the "B" *Sample* container shows no signs of *Tampering* and that the identifying numbers match that on the *Sample* collection documentation. An Independent Witness may be appointed even if the *Athlete* has indicated that he/she will be present and/or represented.

At a minimum, the Laboratory Director or representative and the *Athlete* or his/her representative and/or the Independent Witness shall sign the Laboratory documentation attesting to the above. A refusal of the *Athlete* and/or his/her representative, or of the Independent Witness to sign, and the reasons of the refusal, shall be recorded.

5.3.4.5.4.8.7 The timing of the "B" Confirmation Procedure may be strictly fixed in the short term with no postponement possible, when circumstances justify it. This can notably and without limitation be the case in the context of *Testing* during or immediately before or after Major Events, or when the further postponement of the "B" *Sample* analysis could significantly increase the risk of *Sample* degradation.

5.3.4.5.4.8.8 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"

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[47] The *Athlete* and/or one (1) designated representative, and/or the Independent Witness have the fundamental right to attend the "B" *Sample* opening, aliquoting and resealing procedures. These *Persons* may also have reasonable opportunity to observe other steps of the "B" *Sample* Confirmation Procedure, as long as their presence in the Laboratory does not interfere with the Laboratory's routine operations or Laboratory safety or security requirements. The *Athlete* may however be represented or assisted by a maximum of two (2) representatives during the initial phase of the "B" *Sample* opening procedure.

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

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* Art. 2.5, "*Tampering*, or *Attempted Tampering* with any part of *Doping Control*".

5.3.4.5.4.8.9 The Laboratory shall ensure that, after opening and taking Aliquots for the "B" Confirmation Procedure, the "B" *Sample* is properly resealed in the presence of the *Athlete* or his/her representative or the Independent Witness, as applicable, who shall all sign the Laboratory documentation attesting to the above. If present, the *Athlete* or the *Athlete*'s representative shall be offered the opportunity to select the resealing equipment for the "B" *Sample* container from several identical/sealed items. A refusal of the *Athlete* and/or his/her representative, or of the Independent Witness to sign, and the reasons of the refusal, shall be recorded.

5.3.4.5.4.8.10 If more than one (1) *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker*(s) of the *Use* of a *Prohibited Substance* or *Prohibited Method* has been confirmed in the "A" Confirmation Procedure*,* the Laboratory shall confirm as many of the *Adverse Analytical Findings* as possible given the "B" *Sample* volume available. The decision on the prioritization for the confirmation(s) shall be made to 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 and documented.

5.3.4.5.4.8.11 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. Each repeat confirmation shall be performed using Aliquot(s) different from the one(s) already analyzed. Each Aliquot used shall be recorded.

5.3.4.5.4.8.12 If the final "B" *Sample* confirmation results are negative, the Analytical Testing result shall be considered a Negative Finding. The Laboratory shall notify the Testing Authority 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 five (5) working days [49].

[49] 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 Confirmation Procedures of the "A" and the "B" *Samples*. This does not mean that the "B" confirmation results are negative, as long as the Analyte(s) targeted allows the unequivocal and conclusive identification of the *Prohibited Substance* or *Prohibited Method* in the "B" *Sample*.

5.3.4.5.4.8.13 "B" *Sample* Confirmation Procedure for Non-Threshold Substances and exogenous Threshold Substances

For Non-Threshold Substances (including those with reporting limits as specified in the TD MRPL) and exogenous Threshold Substances, the "B" *Sample* results shall only confirm the "A" *Sample* identification (in compliance with the TD IDCR) for the *Adverse Analytical Finding* to be valid [50]. No quantification or reported estimation of concentrations of such *Prohibited Substance*, or its *Metabolite*(s) or *Marker*(s) is necessary.

5.3.4.5.4.8.14 "B" *Sample* Confirmation Procedure for endogenous Threshold Substances

For endogenous Threshold Substances, *Adverse Analytical Finding* or *Atypical Finding* decisions for the "B" *Sample* results shall be based on the confirmed identification (in accordance with the TD IDCR, applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance or its *Metabolite(s)* or *Marker(s)* and their quantitative determination in the *Sample* at a level exceeding the value of the relevant Threshold as specified in the TD DL or other applicable Technical Document(s) or Laboratory Guidelines. The mean value determined in the "B" *Sample* does not need to be identical to the mean value determined in the "A" *Sample*.

"B" *Sample* quantitative Confirmation Procedures for endogenous Threshold Substances shall be based on the determination of the mean of measured analytical values (*e.g.* concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) "B" *Sample* Aliquots [50]. If there is not enough *Sample* volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

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

5.3.4.5.5 Further Analysis

5.3.4.5.5.1 *Samples* may be selected for Further Analysis at the discretion of the Testing Authority. *WADA* may also direct the Further Analysis of stored *Samples* at its own expense. In such cases, *WADA* shall notify the Testing Authority and Results Management Authority, which shall retain ownership of the *Sample*(s) pursuant to ISTI Art. 10.1.

5.3.4.5.5.2 The choice of which Laboratory will conduct the Further Analysis will be made by the Testing Authority or *WADA*, as applicable.

5.3.4.5.5.3 Requests to the Laboratory for Further Analysis shall be made in writing and be recorded as part of the *Sample*'s documentation.

5.3.4.5.5.4 Further Analysis of *Samples* shall be performed under the ISL, Technical Documents,

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

Technical Letters and Laboratory Guidelines in effect at the time the Further Analysis is performed.

5.3.4.5.5.5 Further Analysis shall, as a matter of principle, be aimed at detecting all the *Prohibited Substance*(s) or *Metabolite*(s) of *Prohibited Substance*(s), or *Marker*(s) of the *Use* of a *Prohibited Substance* or *Prohibited Method* included in the *Prohibited List* in force at the time of the collection of the *Sample*(s). However, Further Analysis shall not be aimed at detecting substances or methods, which are no longer prohibited at the time of Further Analysis.

[Further Analysis may not be applied on a *Sample*, which is the subject of an ongoing Hearing Process, after the responsible *Anti-Doping Organization* has notified the *Athlete* that the *Sample* is a basis for an asserted *Code* Art. 2.1 anti-doping rule violation, without the consent of the *Athlete* or approval from the Hearing Body.

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

When an *Adverse Analytical Finding* has been previously reported in relation to a *Sample* and a *Code* Art. 2.1 anti-doping rule violation has been asserted against the *Athlete* (*i.e*. after results management for a *Code* Art. 2.1 anti-doping rule violation in relation to the *Sample* has been completed), Further Analysis should not seek to detect the *Prohibited Substance*(s) or *Prohibited Method*(s) that were the basis of the previously asserted anti-doping rule violation. Therefore, the *Anti-Doping Organization* requesting the Further Analysis should inform the Laboratory of any previous *Adverse Analytical Finding* reported for the *Sample*(s) subject to Further Analysis. If previously reported *Prohibited Substance*(s) or *Prohibited Method*(s) are detected during the Initial Testing Procedure of Further Analysis, there is no need to conduct the corresponding Confirmation Procedure. However, if the Confirmation Procedure is conducted, and the previously reported *Prohibited Substance(s)* or *Prohibited Method(s)* are confirmed, there is no need to report these results again [51]. If the results are nevertheless reported, this issue shall be addressed by the Results Management Authority during the results management process].

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

Depending on the circumstances, and to ensure an effective and targeted use of the available *Sample* volume, priorities may be set, and/or the scope of the Further Analysis restricted to specific analyses (in particular, but without limitation, to analyses based on new or improved Analytical Testing Procedures).

5.3.4.5.5.7 Further Analysis shall proceed as follows:

- 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

[51] The result should have been already reported in *ADAMS* and should not be reported again. In the absence of initial instructions, the Laboratory shall seek instructions from the Testing Authority or *WADA*, as applicable.

a Presumptive Adverse Analytical Finding, irrespective of the Analytical Testing Procedure applied, and shall be confirmed using the split "B" *Sample* (see below).

- When a Confirmation Procedure is performed on the "A" *Sample* and an *Adverse Analytical Finding* is reported on this basis, the "B" *Sample* Confirmation Procedure shall be applicable (as per ISL Art. 5.3.4.5.4.8).

- Use of the split "B" *Sample*

When the "A" *Sample* is used only for the Initial Testing Procedure(s) or is not used at all during Further Analysis, the "B" *Sample* shall be split and used for analysis. The "B" *Sample* shall be split into two fractions, in accordance with ISL Art. 5.3.1.6. The *Athlete* and/or a representative of the *Athlete* should be invited to witness the splitting procedure. At a minimum, the splitting process shall be conducted in the presence of an appointed Independent Witness.

Even if present during the splitting procedure, the *Athlete* and/or his/her representative has no right to attend the Analytical Testing Procedures to be performed on the first split fraction of the "B" *Sample* (unless the Testing Authority requests otherwise) [52]. In the event an *Adverse Analytical Finding* is notified based on the results of a Confirmation Procedure of the first fraction of the "B" *Sample*, the second split fraction of the "B" *Sample* shall be deemed as the "B" *Sample*. If applicable, a "B" confirmation shall be decided and performed in accordance with ISL Art. 5.3.4.5.4.8.

5.3.4.5.5.8 Further Analysis may be performed on stored *Samples* that were previously reported as having *Adverse Analytical Findings* or *Atypical Findings*. Any new *Prohibited Substance* or *Prohibited Method* detected shall be reported even if the *Athlete* was already sanctioned for a different *Adverse Analytical Finding* [53].

5.3.4.5.5.9 Previously acquired Initial Testing Procedure data may also be re-evaluated for the presence of *Prohibited Substances* or their *Metabolites*(s) or *Markers*(s) of *Prohibited Substances* or *Prohibited Methods*, at the initiative of the Testing Authority, the Results Management Authority, *WADA* or the Laboratory itself. The results of such re-evaluation, if suspicious, shall be communicated to the Testing Authority, the Results Management Authority or *WADA*, as applicable, and may lead to Further Analysis.

5.3.4.5.6 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).

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[52] Since the first split fraction of the "B" *Sample* is considered as an "A" *Sample*, analysis of Aliquots taken from this *Sample* may include the performance of Initial Testing Procedure(s) and "A" Confirmation Procedures or "A" Confirmation Procedures only (if the Initial Testing Procedure(s) was/were already performed using the "A" *Sample*).

[53] See ISL Article 5.3.4.5.5.5 with respect to the reporting of *Prohibited Substance*(s) or *Prohibited Method*(s) previously reported as an *Adverse Analytical Finding*.

5.3.5 Results Management

5.3.5.1 Review of Results

5.3.5.1.1 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.

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

5.3.5.1.3 At a minimum, the review of *Adverse Analytical Findings* and *Atypical Finding*s 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 [54];
- 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.

5.3.5.2 Documentation and Reporting

5.3.5.2.1 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 Technical Document on Laboratory Documentation Packages (TD LDOC).

5.3.5.2.2 Each step of Analytical Testing shall be traceable to the staff member who performed that step.

5.3.5.2.3 Significant deviation from a written SOP shall be recorded.

5.3.5.2.4 Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record.

5.3.5.2.5 Reporting of "A" *Sample* results should occur in *ADAMS* within fifteen (15) working days of receipt of the *Sample*.

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

The reporting time required for specific occasions (*e.g.* Major Events) may be substantially less than fifteen (15) working 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.

5.3.5.2.6 Test Report

5.3.5.2.6.1 The Laboratory shall record the test result for each individual *Sample* in *ADAMS* with the mandatory information stipulated, in compliance with the relevant Technical Document, Technical Letter or Laboratory Guidelines, the items stipulated in ISO/IEC 17025, and the following:

- 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*) – see ISL Art. 5.3.5.2.6.6;
- Specific tests performed, in addition to the Laboratory routine test menu (*e.g.* ESA, GC/C/IRMS, hGH, blood transfusions, DNA, genomic profiling, etc.);
- Any irregularities noted on *Samples*.

5.3.5.2.6.2 The Laboratory is not required to provide any additional Test Report, either in hard copy or digital format, other than the submission in *ADAMS* (except as described in ISL Arts. 5.3.5.2.6.8 and 5.3.5.2.6.12). All *Code*-compliant Testing Authorities shall be able to access the Test Reports of their *Samples* in *ADAMS*. The Laboratory should record the *ADAMS* Test Report as part of the *Sample*'s documentation.

5.3.5.2.6.3 Test Report for Non-Threshold Substances

- "A" *Sample* Test Report

The Laboratory is not required to 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 [55].

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.

[55] When applicable, the Laboratory shall record in the *ADAMS* Test Report the specific *Metabolite*(s) or *Marker*(s) of the Non-Threshold Substance that were identified in the *Sample*.

- "B" *Sample* Test Report

For Non-Threshold Substances, the Laboratory report for the "B" *Sample* shall only establish the presence (*i.e.* the identity) of the *Prohibited Substance*(s) or its *Metabolite*(s) or *Marker*(s) in accordance with the TD IDCR or other applicable Technical Document(s) [55].

However, the Laboratory should provide estimated concentrations, when possible and for information purposes only, if requested by the Testing Authority, Results Management Authority or *WADA,* if the detected level of the Non-Threshold Substance(s), its *Metabolite*(s), or *Marker*(s) may be relevant to 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. Differences in the estimation of the detected levels of Non-Threshold Substance(s), its *Metabolite*(s), or *Marker*(s) between the "A" and "B" Confirmation Procedures do not affect the validity of the reported results.

5.3.5.2.6.4 Test Report for Threshold Substances

- "A" *Sample* Test Report

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 DL, and/or that the *Prohibited Substance*(s) or its *Metabolite*(s) or *Marker*(s) is of exogenous origin.

In the event that the Threshold Substance(s), which are identified as such in the *Prohibited List* and the TD DL, is (are) detected in the presence of (a) diuretic(s) or masking agent(s), the Laboratory shall establish the presence (*i.e.* the identity) of the *Prohibited Substance*(s) and/or its *Metabolite*(s) in accordance with the TD IDCR and the TD DL and report it as an *Adverse Analytical Finding*, in addition to the reporting of the diuretic(s) or masking agent(s). In such cases, the Laboratory should report the estimated concentration of the Threshold Substance(s), indicating that the levels detected may have been impacted by the presence of the diuretic(s) or masking agent(s).

- "B" *Sample* Test Report

For exogenous Threshold Substances, the Laboratory Test Report for the "B" *Sample* shall only establish the presence (*i.e.* the identity) of the *Prohibited Substance*(s) or its *Metabolite*(s) or *Marker*(s) in accordance with the TD IDCR.

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

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

- *Adverse Analytical Finding*; or
- *Atypical Finding*; or
- Negative Finding; or
- Not-Analyzed: any *Sample* received at the Laboratory and not subject to Analytical Testing for a valid, documented reason such as *Sample* irregularities, intermediate *Samples*, etc. (see ISL Arts. 5.3.1.5.2 and 5.3.1.5.3).

5.3.5.2.6.6 The Laboratory shall have a policy regarding the provision of opinions and interpretation of data. An opinion or interpretation may be included in the *ADAMS* Test Report provided that the opinion or interpretation is clearly identified as such. The basis upon which the opinion has been made shall be documented.

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

5.3.5.2.6.7 The Laboratory may request a second opinion from other Laboratory(-ies) before reporting an *Adverse Analytical Finding* or *Atypical Finding*. Such requests for second opinions may be required by specific *WADA* Technical Document(s), Technical Letters or Laboratory Guidelines, required by *WADA* from certain Laboratory(-ies) for all or for specific Analytical Testing Procedures under certain conditions (*e.g.* following a period of Suspension or Analytical Testing Restriction), or requested at the discretion of the Laboratory (*e.g.* for firstly detected Analytes or for difficult to interpret findings). In any case, the request for a second opinion shall be made in writing and recorded as part of the *Sample*'s documentation. Any transfer of data and information necessary for the second opinion shall be made securely and respecting the confidentiality of the analytical data and any other information.

The responsibility for the result shall be of the Laboratory that performed the analysis and issued the final Test Report.

5.3.5.2.6.8 Upon request by *WADA*, the Laboratory shall report a summary of the results of analyses performed in a format specified by *WADA*.

5.3.5.2.6.9 Confidentiality of the analytical data and *Athlete*'s identity shall be observed by all parties (*e.g*. Laboratory, Testing Authority, Results Management Authority, *WADA,* other parties informed including, where different, International Federations, *National Olympic Committees*, National Federations).

5.3.5.2.6.10 Requests for information by the Testing Authority, Results Management Authority or *WADA* to a Laboratory shall be recorded in writing.

5.3.5.2.6.11 Presumptive Adverse Analytical Findings (when applicable – see ISL Art. 5.3.4.5.4.7.3), *Adverse Analytical Findings* and *Atypical Finding*s shall be reported in writing.

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.

5.3.5.2.6.12 The Laboratory shall also provide any information requested by *WADA* in relation to the Monitoring Program (*Code* Art. 4.5).

5.3.5.2.7 Laboratory Documentation Package and Certificate of Analysis

5.3.5.2.7.1 Laboratory Documentation Packages and Certificates of Analysis shall be in compliance with the TD LDOC.

5.3.5.2.7.2 Laboratories are not required to produce a Laboratory Documentation Package for a *Sample* in which no *Prohibited Substance* or *Prohibited Method* or their *Metabolite*(s) or *Marker*(s) was detected.

5.3.5.2.7.3 The Laboratory Documentation Package and/or Certificate of Analysis should be provided by the Laboratory only to the relevant Results Management Authority or *WADA* upon request and should be provided within fifteen (15) working days of the request, unless a different deadline is agreed with the Results Management Authority or *WADA*, respectively.

5.4 Management Requirements

5.4.1 Organization

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

5.4.1.2 The Laboratory Director shall have the responsibilities of the Chief Executive of the Laboratory, unless otherwise noted.

5.4.2 Assuring the Quality of Analytical Results

5.4.2.1 The Laboratory shall participate in the *WADA* EQAS.

5.4.2.2 Analytical performance shall be monitored by operating quality control schemes appropriate to the type and frequency of Analytical Testing performed by the Laboratory. The range of quality control activities include, but are not limited to:

- Appropriate positive and negative quality control samples (QCs) shall be included in every analytical run both for the Initial Testing Procedure(s) and Confirmation Procedure(s) [56];
- Appropriate internal standard(s) shall be used for chromatography methods;

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

- For Threshold Substances, quality control charts (QC-charts) referring to appropriate control limits depending on the Analytical Testing Procedure employed (*e.g.* +/- 2SD; +/- 3SD; +/- $U_{95\%}$), shall be regularly used to monitor method performance and inter-batch variability (when applicable).

5.4.2.3 Internal Quality Assurance Scheme (iQAS)

5.4.2.3.1 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*.

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

5.4.2.3.3 The Laboratory shall have a dedicated SOP for the iQAS program, which incorporates a detailed procedure for the planning, preparation, (blind and/or double-blind) introduction of the iQAS samples and management of the iQAS results (reviewing and follow-up of nonconformities).

5.4.2.4 Internal Audits

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

Internal audit responsibilities may be shared amongst personnel provided that any *Person* does not audit his/her own area.

Internal audits shall be carried out by qualified Laboratory staff members. In addition, qualified members of the Laboratory's host organization (*e.g.*, university, institute, company) may also be included in the internal auditing teams.

5.4.2.5 External Audits

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

5.4.2.6 All quality control procedures shall be documented by the Laboratory.

5.4.3 Management Reviews

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

5.4.4 Document Control

The control of documents that make up the Management System shall meet the requirements of ISO/IEC 17025.

5.4.4.1 The Laboratory Director (or designee) shall approve the Management System documentation and all other documents used by staff members involved in Analytical Testing.

5.4.4.2 The Laboratory shall implement a procedure in its Management System to ensure that the contents of ISL, *WADA* Technical Documents, Technical Letters and Laboratory Guidelines are incorporated into the Laboratory's SOPs by the applicable effective date and that implementation is completed, assessed, audited and recorded. 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.

5.4.5 Control and Storage of Technical Records

5.4.5.1 A copy of all *Samples'* records, including *Sample* and Aliquot chain of custody, instrument records, calculations, etc., shall be kept in a secure storage for a minimum of two (2) years. After two (2) years, and up to ten (10) years, the relevant records shall be kept in secure storage until *Sample* disposal.

5.4.5.2 An electronic copy of the analytical raw data and any data analysis review files shall be stored for ten (10) years for all *Samples*.

5.4.6 Control of Nonconformities in Analytical Testing

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

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

5.4.6.3 Risk Minimization

Laboratories shall take corrective actions in accordance with ISO/IEC 17025 and *WADA* Laboratory Guidelines for Corrective Action Investigation and Reporting.

When conducting a corrective action investigation, the Laboratory shall perform a thorough Root Cause Analysis of the nonconformity.

5.4.6.4 Improvement

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

5.4.7 Reviewing of Requests, Tenders and Contracts

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

5.4.8 Subcontracting of Analysis

5.4.8.1 A Laboratory or WADA-Approved Laboratory for the ABP shall perform all work with qualified personnel and equipment within its accredited or approved facility, respectively.

5.4.8.2 A Laboratory may subcontract an analysis to another Laboratory, in consultation with the Testing Authority (for example, in the case of a specific technology or Analytes that are not within the Laboratory's Scope of ISO/IEC 17025 Accreditation, an Analytical Testing Restriction decision, or as a result of other justifications such as a need for higher sensitivity or specific equipment or expertise, workload or temporary 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 this 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 [57]. 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.

5.4.8.3 When subcontracting an analysis, Laboratories should follow the *WADA* Laboratory Guidelines on "Conducting and Reporting Subcontracted Analysis and Further Analysis for *Doping Control*".

5.4.9 Purchasing of Services and Supplies

5.4.9.1 Chemicals and Reagents

5.4.9.1.1 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 documents. Chemicals, reagents and kits labelled *e.g.* "Research Only" or "Forensic Use Only" may be utilized for the purposes of *Doping Control* as long as they are demonstrated to be Fit-for-Purpose by the Laboratory and/or *WADA.*

5.4.9.1.2 In the case of rare or difficult to obtain Reference Materials, or Reference Collections for use in qualitative Analytical Testing Procedures, the expiration date of the solution 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.

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

5.4.9.1.4 Waste disposal shall be in accordance with national laws and other relevant regulations. This

[57] Or directly contracted by the Testing Authority. In this case, the Laboratory shall nevertheless be in charge of ensuring the *Sample* chain of custody in connection with the transfer of the *Sample* to the other Laboratory or expert as the case may be.

includes biohazard materials, chemicals, controlled substances, and radioisotopes, if used.

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

5.4.10 Cooperation with Customers and with *WADA*

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

5.4.10.2 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 Testing Authorities, which are *Code*-compliant *Anti-Doping Organizations*, as determined by *WADA,* or Sample Collection Authorities working on behalf of *Code*-compliant *Anti-Doping Organizations*] upon request to ensure conformity with the rules established under the *Code* as part of the maintenance of *WADA* accreditation. This information shall be treated in a confidential manner.

5.4.10.3 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 Result 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 Result Management Authority when requested or when there is a potential for misunderstanding of any aspect of the Analytical Testing process, Laboratory Test Report, Certificate of Analysis or Laboratory Documentation Package;
- If requested by the Testing Authority, the Laboratory shall provide advice and/or opinion to the Testing Authority regarding the *Prohibited Substances* and *Prohibited Methods* included in the Analytical Testing Procedures;
- Providing evidence and/or expert testimony on any test result or report produced by the Laboratory as required in administrative, arbitration, or legal proceedings;
- Responding to any complaint submitted by a Testing Authority or Results Management Authority concerning the Laboratory and its operation.

5.4.10.3.1 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.

5.4.11 Complaints

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

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 ISL Art. 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.

6.2.1.1 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*) to be analyzed with specific Analytical Testing Procedure(s), which are not part of the Laboratory's routine Analytical Testing menu;
- As part of *WADA* Laboratory on-site assessments.

6.2.2 Composition of EQAS Samples

EQAS samples may or may not contain Prohibited Substance(s) and/or Metabolite(s) of *Prohibited Substance*(s) and/or *Marker*(s) of *Prohibited Substance*(s) or *Prohibited Method*(s). Laboratories shall analyze these samples using their routine Initial Testing Procedures and Confirmation Procedures.

6.2.2.1 Blank EQAS Samples

Blank EQAS samples do not contain *Prohibited Substances* or their *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* [58].

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*.

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

These EQAS samples are distributed to Laboratories and WADA-Approved Laboratories for the ABP on a regular basis (*e.g.* monthly) with the purpose of evaluating their proficiency in the analysis and reporting of the blood *Markers* that constitute the hematological module of the *ABP*.

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

- 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 reporting limits, as per TD MRPL);
- Non-Threshold Substances with reporting limits as stated in the TD MRPL (*e.g.* substances prohibited *In-Competition* only), will normally be present in estimated concentrations greater than 120% of the applicable reporting limit;
- Concentrations of the *Prohibited Substance* and/or its *Metabolite*(s) or *Marker*(s) below 50% of the applicable MRPL (for Non-Threshold Substances prohibited at all times with no reporting limits, for educational purposes).

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

- 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.

[58] To the extent possible (in consideration, for example, of ethical constraints, availability of the pharmaceutical grade substance, etc.), double-blind EQAS samples containing *Prohibited Substance*(s) and/or *Metabolite*(s) of *Prohibited Substance*(s) and/or *Marker*(s) of *Prohibited Substance*(s) or *Prohibited Method*(s) should be prepared from controlled administration studies.

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

6.3 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 Analytical Testing Procedures applied in routine Analytical Testing).

6.4 Reporting of EQAS results

The purpose of the EQAS program is to ensure that all Laboratories maintain proficiency in the performance of their Analytical Testing Procedures and report the results to *WADA* and the Testing Authority in a timely manner.

A Laboratory shall not communicate with other Laboratories regarding the identity or content of substances present in or absent from blind EQAS samples prior to the submission of EQAS results to *WADA*. This prohibition also applies to Laboratory requests for second opinions, which shall not be requested for blind EQAS samples.

Contact between Laboratories regarding any aspect of blind EQAS analysis (including the results obtained) prior to reporting by all Laboratories to *WADA* will be considered an attempt to circumvent the quality assessment. Engaging in such discussions will subject the Laboratories involved to disciplinary procedures, which may lead to Suspension or Revocation of *WADA* accreditation.

For double-blind EQAS samples, which are indistinguishable from routine *Samples*, consultation between Laboratories before reporting such EQAS results to *WADA* may occur. However, such consultation shall not involve identifying the sample as a *WADA* double-blind EQAS sample (in cases when, for any reason, the Laboratory identifies the EQAS nature of the sample).

6.4.1 Reporting Blind EQAS Results

The Laboratory shall report the results of blind EQAS samples to *WADA* in *ADAMS* in the same manner as specified for routine *Samples* (see ISL Art. 5.3.5.2.6) unless otherwise notified by *WADA*. For some blind EQAS samples or sample sets, additional information may be requested from the Laboratory (*e.g.* LODs, LOQs, MU estimations, etc.).

The results of the blind EQAS shall be submitted to *WADA* on or before the specified date unless an extension is granted by *WADA* for valid reasons. For a failure to report results of blind EQAS samples within the established deadline, without prior approval by *WADA*, the Laboratory shall receive two (2) penalty points, and an additional two (2) penalty points per week beyond the applicable deadline (refer to the ISL Points System Table in Art. 7.3).

6.4.2 Reporting Double-Blind EQAS Results

The Laboratory shall report the results of double-blind EQAS samples in *ADAMS* as per ISL Art. 5.3.5.2.6.

Reporting of results should occur within fifteen (15) working days of receipt of the samples, unless an extension has been agreed with the Testing Authority after the Laboratory has provided the Testing Authority with a valid reason for the delay in the reporting of the results.

Subject to an extension of the above deadline by agreement or otherwise, or to a request based on justified grounds, as determined by *WADA*, failure to report results of double-blind EQAS samples in *ADAMS* within thirty (30) calendar days of receipt of the samples, shall carry two (2) penalty points and an additional two (2) penalty points per week beyond the applicable deadline (refer to the ISL Points System Table in Art. 7.3).

6.4.3 Reporting Educational EQAS Results

The Laboratory shall report the results of open or blind educational EQAS samples on or before the specified reporting deadline and in a format specified by *WADA*. Results received after the deadline will not be included in the assessment of EQAS results nor in the subsequent educational EQAS report.

6.4.4 Reporting Results for EQAS Samples Containing Non-Threshold Substance

6.4.4.1 Unless otherwise specified by *WADA* (for example, for educational EQAS), the report of EQAS results for Non-Threshold Substances shall include all the Analytes whose presence in the EQAS sample has been confirmed by the Laboratory in accordance with the TD IDCR, including the *Prohibited Substance*(s) (*i.e*. parent compound(s), if applicable) and all identified *Metabolite*(s) and/or *Marker*(s) of the *Prohibited Substances* or *Marker*(s) of *Prohibited Method*(s). *WADA* may also require that the Laboratory report the estimated concentrations of the confirmed Analyte(s).

6.4.4.2 For open educational and blind EQAS samples, the Laboratory shall report the LODs of the identified Non-Threshold Substance(s) and/or *Metabolite*(s) and/or *Marker*(s), or of the identified *Marker*(s) of *Prohibited Method*(s), as estimated during method validation of the Initial Testing Procedure.

6.4.5 Reporting Results for EQAS Samples Containing Threshold Substances

6.4.5.1 For educational and blind EQAS samples, the report of EQAS results for Threshold Substances shall include the values measured for each Aliquot analyzed, whenever the measured mean value of all replicates is greater than or equal to 50% of the applicable Threshold.

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

6.4.5.2 For double-blind EQAS samples, the Laboratory shall report the quantitative results in *ADAMS* as done for routine *Samples*, in accordance with the relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines.

7.0 Evaluation of Laboratory EQAS and Routine Analytical Testing Performance

The *WADA* system of Laboratory EQAS and routine Analytical Testing performance (see ISL Points Scale Table in ISL Art. 7.3 below) has been developed by the *WADA* LabEG with the objective of setting a transparent and balanced procedure for evaluation of Laboratory and probationary laboratory operations. It is based on the principle of proportionality and is focused on improving Laboratory's Analytical Testing capabilities and, in the case of probationary laboratories, their readiness for obtaining *WADA* accreditation. It is ultimately aimed at maintaining the confidence in and strengthening of the anti-doping Laboratory system to benefit clean *Athletes*.

7.1 Evaluation of EQAS Results

Satisfactory EQAS performance in single EQAS rounds [59] and over a consecutive 12-month period [60] is necessary for maintaining *WADA* accreditation.

Unsatisfactory performance in an educational EQAS for a new or *WADA*-specific [61] Analytical Testing Procedure may prevent the Laboratory from seeking an extension of the Laboratory's Scope of ISO/IEC 17025 Accreditation for the Analytical Testing Procedure and from its application in routine Analytical Testing (see ISL Art. 4.4.2.2). The Laboratory may only apply the newly *WADA*-approved method or procedure for routine *Sample* analysis when it properly corrects the deficiencies identified in the educational EQAS (as determined by *WADA*) and the method is included in the Laboratory's Scope of ISO/IEC 17025 Accreditation.

7.1.1 EQAS Samples Containing Non-Threshold Substances

7.1.1.1 When a qualitative determination of a Non-Threshold Substance has been reported, the Laboratory result will be evaluated on the basis of the correct reporting of the finding (*e.g. Adverse Analytical Finding*, Negative Finding) as intended in the preparation of the EQAS sample.

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

[60] The 12-month period to account for the total number of penalty points accumulated by a Laboratory or probationary laboratory according to the ISL Points Scale Table is defined as the most recent consecutive 12-month interval starting either from the date that the Laboratory or the probationary laboratory reported the result (EQAS or routine Analytical Testing, as applicable) in *ADAMS* or from the date that the Laboratory or probationary laboratory is informed, in writing, of the assigned penalty points total by *WADA*, whichever is more favorable to the Laboratory or the probationary laboratory. Any assigned penalty points will expire after a 12-month period; however, the total number of penalty points within any consecutive 12-month period shall not reach the maximum allowed number of penalty points established in the ISL Points Scale Table.

[61] Some Analytical Testing Procedures are not eligible for a Flexible Scope of ISO/IEC 17025 Accreditation and require specific *WADA* approval before the Laboratory can apply the procedure to the analysis of *Samples*. *WADA* approval will be based on its assessment of the Fitness-for-Purpose of the Analytical Testing Procedure, validation by the Laboratory, and the successful Laboratory participation in an inter-laboratory collaborative study or *WADA* EQAS round. *WADA* will communicate which Analytical Testing Procedures fall into this category to the Laboratories and to the Accreditation Bodies (see ISL Article 4.4.2.2).

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

7.1.1.3 The results for any Non-Threshold Substance and/or its *Metabolite*(s) and/or *Marker*(s) at concentrations between 50% of the MRPL and the MRPL (or less than 120% of the reporting limit, when applicable) shall not be considered for evaluation for the purposes of the EQAS points system. However, *WADA* may require an internal investigation and Corrective Action Report from the Laboratory.

7.1.1.4 The results for any Non-Threshold Substance and/or its *Metabolite*(s) and/or *Marker*(s) at concentrations below 50% of the applicable MRPL in an EQAS sample shall not be evaluated for the purposes of the EQAS points system. Nonetheless, the Laboratory should report their finding(s) if the analyses are compliant with its validation data, SOPs, the ISL and the TD IDCR. Laboratories unable to report such substance(s) are encouraged, on receipt of the EQAS report, to consider re-assessment of their Analytical Testing Procedure.

7.1.2 EQAS Samples Containing Threshold Substances

7.1.2.1 For EQAS samples containing Threshold Substances at levels greater than 50% of the Threshold, the quantitative determination will be statistically evaluated to determine the compatibility of the reported result with the assigned value (reference, nominal or consensus value, as applicable) through *e.g. z*-score, degree of equivalence analysis. Results shall be evaluated as per the ISL Points Scale Table [62].

This provision does not apply to the reporting of results for certain exogenous Threshold Substances, identified in the TD DL, if detected in the presence of diuretics or masking agents. In such cases, the detection and identification of the exogenous Threshold Substance shall be reported in accordance with the TD DL. The failure to report the presence of the Threshold Substance(s), as applicable, will be considered as a False Negative Finding.

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.

[62] The main criterion applied for the evaluation of EQAS results for the quantification of Threshold Substances is the compatibility of the reported Laboratory result with the assigned value. Therefore, the incorrect reporting of an EQAS sample as a Negative Finding or as an *Adverse Analytical Finding*, as applicable, when the assigned value of the Threshold Substance in the EQAS sample is close to the Decision Limit, is not considered as a False Negative Finding or False *Adverse Analytical Finding*, respectively, if the absolute *z*-score (truncated to two (2) significant figures) for the Laboratory quantitative result is < 3.0 [see footnote 73].

7.1.2.2 Unsatisfactory Quantitative Result (absolute *z*-score ≥ 3) [63]

The Laboratory shall provide *WADA* with a satisfactory Corrective Action Report [64] for an unsatisfactory quantitative result. The Corrective Action Report shall be submitted within ten (10) working days of receiving a written notification about the unsatisfactory result from *WADA*. Failure to submit a satisfactory Correction Action Report or the late submission of the Correction Action Report without prior approval by *WADA* shall result in the imposition of further penalty points in accordance with the ISL Points Scale Table.

7.1.2.3 Questionable Quantitative Result (absolute *z*-score > 2 and < 3)

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

7.2 Evaluation of Laboratory Performance

7.2.1 False *Adverse Analytical Finding*

7.2.1.1 A False *Adverse Analytical Finding* is not acceptable for any blind or double-blind EQAS sample or during the course of routine Analytical Testing conducted by a Laboratory.

7.2.1.2 False *Adverse Analytical Finding* during routine Analytical Testing

If the Laboratory discovers that it reported a False *Adverse Analytical Finding* during routine Analytical Testing, the Laboratory shall inform *WADA* immediately.

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[63] The *z*–score is calculated according to the following formula and truncated to two (2) significant figures:

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

Where:

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

[64] A Corrective Action Report will be considered as satisfactory when it meets all of the following criteria, as determined by the LabEG:

- Properly and concisely identifies the root cause(s) of the nonconformity, following an appropriate investigation into all the factors that may have caused the problem (Root Cause Analysis);
- Leads to the documented implementation of effective corrective action(s) to solve the problem; and
- Leads to the documented implementation of appropriate preventive actions, if applicable, to minimize the risk of recurrence of the problem.

A satisfactory Corrective Action Report shall include only the necessary supporting documentation (*e.g.* raw analytical data, data review files, evidence of procurement of Reference Materials) which demonstrates the implemented actions described in the Corrective Action Report.

When the False *Adverse Analytical Finding* is identified by *WADA,* based on information received from a Testing Authority, a Results Management Authority, through *WADA*'s own results management activities or through any other means, *WADA* shall inform the Laboratory immediately.

In either case, the Laboratory shall cease all Analytical Testing activities applied to the affected Analytical Testing Procedure(s) and/or Laboratory process(es) (*e.g. Sample* aliquoting, reporting of results) as soon as it becomes aware or is informed by *WADA* that a False *Adverse Analytical Finding* has been reported.

The Laboratory shall provide *WADA* with a Corrective Action Report, including a Root Cause Analysis of the incorrect results and the corrective action(s) implemented for its rectification, within five (5) working days of informing *WADA* or been informed by *WADA*, as applicable, or, in exceptional cases, as otherwise agreed with *WADA*.

The *WADA* LabEG shall review the Laboratory's Corrective Action Report within five (5) working days, or within a timeline otherwise determined by *WADA*, and establish the source of the incorrect result as either a technical/methodological error or a clerical/administrative error.

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* during the preceding twelve (12) months (or during a period otherwise determined by *WADA*) within five (5) working days (unless informed otherwise by *WADA*) [65]. Depending on the 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.

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

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

If the 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 ISL 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* [66].

The LabEG, considering the nature of the error that caused the False *Adverse Analytical Finding* result, shall make a recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's *WADA* accreditation or to impose an Analytical Testing Restriction against the Laboratory for a particular Analytical Testing Procedure or for the analysis of a particular class of *Prohibited Substances* or *Prohibited Methods*, as applicable [67].

7.2.1.2.2 False *Adverse Analytical Finding* with No *Consequences* being imposed on an *Athlete*

- Technical or methodological error

If the Root Cause Analysis investigation performed by the Laboratory identifies the error as technical or methodological, the Laboratory will be initially imposed twenty (20) penalty points in accordance with the ISL Points Scale Table. However, if the Laboratory first informs (*i.e.* voluntarily self-reports) *WADA* of their investigation and discovery of a False *Adverse Analytical Finding*, then the Laboratory will have five (5) points deducted from the twenty (20) penalty points initially assigned.

If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with *WADA*). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, then the Laboratory will be assigned an additional five (5) penalty points and the LabEG shall make a recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's

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[66] *WADA* shall inform a Laboratory in writing about the imposition of penalty points, as decided by the LabEG and in accordance with the ISL Points Scale Table. If the final decision regarding the number of penalty points to be imposed is conditional on the evaluation of corrective actions or other follow-up measures (*e.g.* analysis of further EQAS samples) requested by the LabEG, *WADA* will only inform the Laboratory about the final number of penalty points imposed at the end of the evaluation process [*e.g.* 5 penalty points at the end of the evaluation process of a False Negative Finding resolved through the timely implementation of satisfactory corrective action(s)].

[67] During the period of Suspension, the Laboratory shall follow the instructions provided in ISL Article 4.6.5.2 in regard to *Samples* in Laboratory's possession at the time of the Suspension. On the other hand, if an Analytical Testing Restriction has been imposed, the Laboratory shall subcontract the affected analyses as provided in ISL Arts. 4.6.5.1 and 5.4.8.

During the Suspension or Analytical Testing Restriction period, *WADA* will conduct an on-site assessment of the Laboratory's activities, including the analysis of further EQAS samples.

The Suspension or Analytical Testing Restriction of the Laboratory shall be lifted only when the aforementioned conditions are satisfactorily completed, and the Laboratory provides sufficient evidence, as determined by *WADA*, that appropriate steps have been taken to remedy the issue(s) that resulted in the Suspension or Analytical Testing Restriction.

WADA accreditation or to impose an Analytical Testing Restriction against the Laboratory for a particular Analytical Testing Procedure or for the analysis of a particular class of *Prohibited Substances* or *Prohibited Methods*, as applicable [67].

However, if the Laboratory is able to remedy the technical or methodological error through the implementation of satisfactory corrective actions in a timely manner, as determined by the LabEG, the Laboratory will have ten (10) penalty points deducted, in accordance with the ISL Points Scale Table. The Laboratory will be informed by *WADA*, in writing, of the final amount of penalty points assigned in connection with the reporting of the False *Adverse Analytical* Finding [66]. Provided that the point total accumulated by the Laboratory for a 12-month [60] period does not exceed thirty (30) points, the Laboratory will be able to resume Analytical Testing activities following written notification by *WADA.*

- Clerical/Administrative Error [68]

If the Root Cause Analysis investigation performed by the Laboratory identifies the error as clerical or administrative, the Laboratory will be initially assigned fifteen (15) penalty points in accordance with the ISL Points Scale Table. However, if the Laboratory first informs (*i.e.* voluntarily self-reports) *WADA* of their investigation and discovery of a *False Adverse Analytical Finding*, then the Laboratory will have five (5) points deducted from the fifteen (15) penalty points initially assigned.

If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with *WADA*). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, the Laboratory shall receive an additional ten (10) penalty points in accordance with the ISL Points Scale Table. The LabEG, considering the nature of the clerical/administrative error that caused the False *Adverse Analytical Finding* result, shall make a recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's *WADA* accreditation or to impose an Analytical Testing Restriction against the Laboratory, as applicable [67].

However, if the Laboratory is able to remedy the clerical or administrative error through the implementation of satisfactory corrective actions in a timely manner, as determined by the LabEG, the Laboratory will have ten (10) additional penalty points deducted, in accordance with the ISL Points Scale Table. The Laboratory will be informed by *WADA*, in writing, of the total amount penalty points assigned in connection with the reporting of the False *Adverse Analytical* Finding [66]. Provided that the point total accumulated by the Laboratory for a 12-month [60] period does not exceed thirty (30) points, the Laboratory will be able to resume Analytical Testing activities following written notification by *WADA.*

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

7.2.1.3 False *Adverse Analytical Finding* for blind or double-blind EQAS sample

In the event that a False *Adverse Analytical Finding* is reported during the EQAS, *WADA* will immediately start an investigation to establish if the incorrect result was caused by the EQAS sample provider (blind and double-blind EQAS) or the Testing Authority (double-blind EQAS).

If it is established that the False *Adverse Analytical Finding* result was caused by an error made by the EQAS sample provider or the Testing Authority, the Laboratory will be informed by *WADA* and no further action will be required from the Laboratory.

If the *WADA* investigation indicates that the False *Adverse Analytical Finding* was caused by an error made by the Laboratory during the Analytical Testing of the EQAS sample(s), the Laboratory shall be informed by *WADA* as soon as possible. However, if the False *Adverse Analytical Finding* is related to the analysis of a double-blind EQAS sample and the Laboratory first informs (*i.e.* voluntarily self-reports) *WADA* of their investigation and discovery of a False *Adverse Analytical Finding*, this will be taken into consideration when evaluating the Laboratory's performance in accordance with the ISL Points Scale Table (see below).

The Laboratory shall provide *WADA* with a Corrective Action Report, including a Root Cause Analysis of the incorrect result(s) and corrective action(s) implemented for its rectification, within ten (10) working days of being informed by *WADA* (unless otherwise indicated by *WADA*). In addition, the Laboratory may be required by *WADA* to analyze additional EQAS samples and/or to review the analytical results and to re-analyze any relevant and available *Samples* previously reported as *Adverse Analytical Findings* during the preceding twelve (12) months (or during a period otherwise determined by *WADA*) **[65]**, within five (5) working days (unless informed otherwise by *WADA*). Depending on the nature of the error that caused the false *Adverse Analytical Finding*, this re-analysis may be limited to one Analyte, a class of *Prohibited Substances* or *Prohibited Methods*, or may include any *Prohibited Substance* or *Prohibited Method*. A statement signed by the Laboratory Director shall record this re-analysis. The Laboratory will be required to inform all of its clients whose Analytical Testing results may have been affected.

The *WADA* LabEG shall review the Laboratory's Corrective Action Report within ten (10) working days, or within a timeline otherwise determined by *WADA.*

- Technical or methodological error

If the Root Cause Analysis investigation performed by the Laboratory identifies the error as technical or methodological, the Laboratory will be initially imposed twenty (20) penalty points in accordance with the ISL Points Scale Table. However, if the False *Adverse Analytical Finding* is related to the analysis of a double-blind EQAS sample and the Laboratory first informs (*i.e.* voluntarily self-reports) *WADA* of their investigation and discovery of a *False Adverse Analytical Finding*, then the Laboratory will have five (5) points deducted from the twenty (20) penalty points initially assigned.

If the Laboratory's Corrective Action Report for the technical or methodological error is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with *WADA*). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, then the Laboratory will be assigned an additional five (5) penalty points and the LabEG shall make a recommendation to the Chair of the *WADA*

Executive Committee to suspend the Laboratory's *WADA* accreditation or to impose an Analytical Testing Restriction against the Laboratory for a particular Analytical Testing Procedure or for the analysis of a particular class of *Prohibited Substances* or *Prohibited Methods*, as applicable [67].

However, if the Laboratory is able to remedy a technical/methodological error through the implementation of satisfactory corrective action(s) in a timely manner, as determined by the LabEG, the Laboratory will have ten (10) penalty points deducted, in accordance with the ISL Points Scale Table. The Laboratory will be informed by *WADA*, in writing, of the final amount of penalty points assigned in connection with the reporting of the False *Adverse Analytical* Finding [66].

- Clerical/Administrative Error [68]

If the Root Cause Analysis investigation performed by the Laboratory identifies the error as clerical or administrative, the Laboratory will be initially imposed fifteen (15) penalty points in accordance with the ISL Points Scale Table. However, if the False *Adverse Analytical Finding* is related to the analysis of a double-blind EQAS sample and the Laboratory first informs (*i.e.* voluntarily self-reports) *WADA* of their investigation and discovery of a *False Adverse Analytical Finding*, then the Laboratory will have five (5) points deducted from the fifteen (15) penalty points initially assigned.

If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with *WADA*). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, the Laboratory shall receive an additional ten (10) penalty points in accordance with the ISL Points Scale Table. The LabEG, considering the nature of the clerical/administrative error that caused the False *Adverse Analytical Finding* result, shall make a recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's *WADA* accreditation or to impose an Analytical Testing Restriction against the Laboratory, as applicable [67].

However, if the Laboratory is able to remedy the clerical or administrative error through the implementation of satisfactory corrective action(s) in a timely manner, as determined by the LabEG, the Laboratory will have ten (10) points deducted, in accordance with the ISL Points Scale Table. Consequently, the Laboratory will be informed by *WADA*, in writing, of the final amount of penalty points assigned in connection with the reporting of the False *Adverse Analytical Finding* [66].

The reporting of any False *Adverse Analytical Finding* Result, irrespective of whether it relates to routine Analytical Testing or the EQAS, or whether or not it results in the Suspension of a Laboratory's *WADA* accreditation or an Analytical Testing Restriction, may trigger a *WADA* Laboratory on-site assessment and the requirement that additional EQAS samples be analyzed by the Laboratory.

7.2.2 False Negative Finding

Laboratories failing to identify and/or report a *Prohibited Substance* and/or its *Metabolite*(s) or the *Marker*(s) of a *Prohibited Substance* or a *Prohibited Method* in a blind 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 ISL Points Scale Table. However, if the False Negative Finding is related to the analysis of a routine *Sample* or a double-blind EQAS sample and the Laboratory first informs (*i.e.* voluntarily self-reports) *WADA* of their investigation and discovery of a False Negative Finding, then the Laboratory will have five (5) points deducted from the ten (10) penalty points initially assigned.

The Laboratory shall provide *WADA* with a Corrective Action Report within ten (10) working days (unless otherwise indicated by *WADA*).

The LabEG shall review the Laboratory's Corrective Action Report within ten (10) working days, or within a timeline otherwise determined by *WADA*, and take the following steps, where appropriate:

- If the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG, the LabEG shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within five (5) working days (or as otherwise agreed with *WADA*). If the Laboratory is unable to resubmit a satisfactory revised Corrective Action Report in a timely manner, as determined by the LabEG, the Laboratory shall receive an additional five (5) penalty points in accordance with the ISL Points Scale Table. In addition, *WADA* will request the Laboratory to analyze additional (blind and/or double-blind) EQAS sample(s). Depending on the nature of the error that caused the False Negative Finding, this re-analysis may be limited to one Analyte, a class of *Prohibited Substances* or *Prohibited Methods*, or may include any *Prohibited Substance* or *Prohibited Method*.

  The Laboratory shall report correct results for the analysis of all EQAS samples. In addition, the Laboratory shall implement satisfactory corrective action(s) (as determined by *WADA*) which ensures that the cause(s) of the nonconformity is eliminated, thus avoiding repetition of the mistake in the future. Failure by the Laboratory to report correct results for the additional EQAS sample(s) will incur the imposition of additional penalty points in accordance with the ISL Points Scale Table. The LabEG, considering the nature of the error that caused the False Negative Finding, shall make a recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's *WADA* accreditation or to impose an Analytical Testing Restriction against the Laboratory, as applicable [67].

- However, if the Laboratory is able to remedy the issue(s) that led to the reporting of the False Negative Finding, through the implementation of satisfactory corrective actions in a timely manner, as determined by the LabEG, five (5) penalty points initially imposed will be deducted, in accordance with the ISL Points Scale Table. Consequently, the Laboratory will be informed by *WADA*, in writing, of the final amount of penalty points assigned in connection with the reporting of the False Negative Finding [66].

  The reporting of False Negative Finding(s), irrespective of whether it relates to routine Analytical Testing or the EQAS, or whether or not it results in the Suspension of a Laboratory's *WADA* accreditation or an Analytical Testing Restriction, may trigger a *WADA* Laboratory on-site assessment and the requirement that the Laboratory analyses additional EQAS samples.

7.2.3 Further Procedural Evaluations [69]

If the LabEG considers that a Corrective Action Report is unsatisfactory, and the Laboratory is not able to provide a satisfactory revised Corrective Action Report within a reasonable time frame after receiving feedback from the LabEG, the Laboratory will receive two (2) penalty points.

Corrective Action Reports related, for example, to nonconformities detected during Laboratory on-site assessments, or to procedural or reporting nonconformities with the ISL, Technical Documents or Technical Letters, or unsatisfactory performance in the analysis of EQAS samples (not related to a False *Adverse Analytical Finding* or False Negative Finding), shall be submitted to *WADA* within thirty (30) calendar days of *WADA*'s notification to the Laboratory. Late submission of Corrective Action Reports, as determined by the LabEG, will result in the imposition of one (1) additional penalty point per five (5) working days beyond the applicable deadline, unless the Laboratory provides valid reasons for the delay, as determined by the LabEG.

Unless otherwise agreed with *WADA*, the corrective and preventive action(s) reported to and approved by *WADA* shall be implemented in the routine operations of the Laboratory immediately.

7.3 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 ISL Points Scale Table.

The accumulation of the maximum allowed number of penalty points for the EQAS and/or routine Analytical Testing, as determined in the ISL Points Scale Table below, shall prompt the *WADA* LabEG to make a recommendation to the Chair of the *WADA* Executive Committee to impose an Analytical Testing Restriction against the Laboratory or to impose a Suspension of the Laboratory's *WADA* accreditation, as applicable.

When the Laboratory's WADA accreditation is suspended, any 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 [70]. However, when an Analytical Testing Restriction is imposed against a Laboratory, any penalty points not related to the Analytical Testing Restriction, which were accumulated up to the imposition of the Analytical Testing Restriction or further accumulated during the Analytical Testing Restriction period (within a 12-month period [60]), 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.

[69] ISL Article 7.2.3 does not apply to the evaluation of Corrective Action Reports for False *Adverse Analytical Findings* or False Negative Findings, which are covered in ISL Arts. 7.2.1 and 7.2.2, respectively.

[70] This provision doesn't apply to a voluntary cessation of Laboratory operations (see ISL Art. 4.6.7).

ISL Points Scale Table for Assessment of Laboratory and Probationary Laboratory Performance

Analytical Testing Conditions	Nonconformity	Type of Error Outcome	Penalty Points	Actions and Sanctions
Routine Analytical Testing (ISL Art 7.2.1.2.1)	**False *AAF*** **+** ***Consequence* for the *Athlete*** **No *Consequence* for the *Athlete***	**Technical / Methodological error** or **Clerical / Administrative error**	**20**	**Cease Analytical Testing** and **Suspension / Analytical Testing Restriction**
Routine Analytical Testing (ISL Art 7.2.1.2.2) Or **EQAS (blind or double blind) round** (ISL Art 7.2.1.3)	**False *AAF*** **+** **No *Consequence* for the *Athlete***	**Technical / Methodological error**	**20**	**Cease Analytical Testing**
		• Self-reporting [71]	**- 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 [71]	**- 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** (ISL Art 7.2.2)	**False Negative Finding**	**10**	**additional EQAS samples [72]**
		• Self-reporting [71]	**- 5**	
		• Satisfactory and timely CAR	**- 5**	
		• Unsatisfactory CAR	**+ 5**	

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

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

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 [73] Unsatisfactory CAR		**5**
	|*z*-score| ≥ 3.0 [73] Satisfactory and timely CAR		**0**
Documentation* or Technical Issue** (per occurrence)	**ISL, TD or TL Nonconformity**		**2**
	Unsatisfactory CAR		**2**
	Late Submission of CAR (per 5 working days beyond the deadline)		**1**
	Late reporting of blind or double-blind EQAS results (per 5 working days beyond the deadline)		**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**		
Point Total for routine Analytical Testing** for 12-month period**		
Point Total (blind and double-blind EQAS and routine Analytical Testing)** for 12-month period**	**≥ 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.

AAF – Adverse Analytical Finding; CAR - Corrective Action Report

[73] When an unsatisfactory (|z-score| ≥ 3.0) quantification result leads to the misreporting of the EQAS sample as a False *Adverse Analytical Finding* or as a False Negative Finding, then penalty points will be assigned in accordance with ISL Articles 7.2.1.3 and 7.2.2, respectively.

7.4 Probationary Period and Probationary Laboratory Evaluation

The probationary EQAS is a part of the initial evaluation of a probationary laboratory seeking *WADA* accreditation. In addition to providing blind EQAS samples, *WADA* may provide, upon request, samples from past EQAS rounds in order to allow the probationary laboratory an opportunity to evaluate its performance against the recorded performance of Laboratories. Composition of the probationary EQAS samples corresponds to the criteria described in ISL Art. 6.2.2.

Successful participation in *WADA* probationary EQAS, based on the ISL Points Scale Table (less than twenty (20) points accumulated within a single blind EQAS round and less than thirty (30) points for the most recent and consecutive twelve (12) month [60] period) is required before a probationary laboratory is eligible to be considered for *WADA* accreditation. The LabEG may decide, based on its evaluation of the overall performance of the probationary laboratory, to extend the probationary period of accreditation, even if the probationary laboratory did not reach the maximum number of penalty points based on the ISL Points Scale Table. However, once a laboratory is granted *WADA* accreditation, penalty points accumulated during the probationary period are annulled and are not carried forward onto the accredited phase.

The blind EQAS samples shall be distributed in multiple rounds 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. *WADA* may decide to send a set of EQAS samples and/or audit 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) working 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 ISL 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 [60] period (*e.g*. at least fifteen (15) blind EQAS samples), and provided that all of other necessary conditions have been fulfilled, the laboratory will be audited by an assessment team appointed by *WADA*.

This assessment will take place while the probationary laboratory is processing and analyzing a minimum of a further fifteen (15) blind EQAS samples supplied by *WADA* as part of a Final Accreditation Test (FAT). 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 on-site assessment and/or the analytical performance and/or the presentation of the requested Laboratory Documentation Package(s) shall be submitted within thirty (30) calendar 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) calendar 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 ISL Art. 4.2).

PART THREE: ISL ANNEXES

ISL ANNEX A - CODE OF ETHICS FOR LABORATORIES and WADA-APPROVED LABORATORIES FOR THE ABP

1.0 Confidentiality

Directors of Laboratories and WADA-Approved Laboratories for the ABP, their delegates and all Laboratory staff shall respect and comply with *Code* Art. 14.3.5.

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 [74] and the program(s) have received proper ethical approval, if applicable.

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

2.1 Research on Human Subjects

The Laboratories and WADA-Approved Laboratories for the ABP shall follow the Helsinki Accords and any applicable national standards as they relate to the involvement of human subjects in research. Voluntary informed consent shall also be obtained from human subjects in any drug administration studies for the purpose of development of a Reference Collection or proficiency testing materials.

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

3.1 Analytical Testing for *Anti-Doping Organizations*

The Laboratories and WADA-Approved Laboratories for the ABP shall accept *Samples* for Analytical Testing only if all of the following conditions 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 WADA-Approved Laboratory for the ABP in accordance with the ISTI;
- The collection is a part of an anti-doping program; and
- The Testing Authority is a *Code*-compliant *Anti-Doping Organization*.

[74] The Laboratory shall not engage in any research activity that undermines or is detrimental to the World Anti-doping Program.

3.2 Clinical or Forensic Analysis

3.2.1 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 sample is for medical diagnostic or therapeutic purposes.

3.2.2 Work to aid in forensic and/or legal investigations may be undertaken but due diligence should be exercised to ensure that the work is requested by an appropriate agency or 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

3.3 Other Analytical Activities

3.3.1 The Laboratory or WADA-Approved Laboratory for the ABP shall not engage in any analysis or activity that undermines or is detrimental to the World Anti-doping Program [75].

3.3.2 Laboratories and WADA-Approved Laboratories for the ABP shall not accept *Samples* from individual *Athletes* on a private basis or from individuals or organizations acting on their behalf.

3.3.3 If the Laboratory or WADA-Approved Laboratory for the ABP accepts *Samples* from any entity that is not a *Code*-compliant *Anti-Doping Organization*, it is the responsibility of the Director of the Laboratory or WADA-Approved Laboratory for the ABP to receive assurance, in writing, that any *Adverse Analytical Finding* or *Adverse Passport Finding* will follow an appropriate results management process and that the results cannot be used in any way by an *Athlete* or associated *Person* to avoid the detection of doping.

3.3.4 The Laboratory or WADA-Approved Laboratory for the ABP shall not provide analytical services in a *Doping Control* adjudication, unless specifically requested by the responsible Testing Authority, *WADA* or a Hearing Body.

3.3.5 The Laboratory shall not engage in analyzing commercial material or preparations (*e.g*. dietary or herbal supplements) unless specifically requested by an *Anti-Doping Organization* or *WADA* as part of a research program or results management process.

3.3.6 If a request pursuant to Art. 3.3.5 is made by an *Athlete*, the Laboratory may conduct the analysis if agreed by the *Anti-Doping Organization* or *WADA*, which may also specify conditions that must be followed prior to or during the analysis (*e.g.* verification of original sealed packages). The Laboratory shall not provide results, documentation or advice that, in any way, could be used as an endorsement of products or services.

Analytical activities performed under Arts. 3.2 and 3.3 above will not fall under the *WADA* accredited or approved status of the laboratory. A Laboratory or WADA-Approved Laboratory for the ABP shall only

[75] The World Anti-Doping Program comprises the anti-doping programs of *WADA* and all *Code Signatories*, including International Federations, *National Anti-Doping Organizations*, *Regional Anti-Doping Organizations*, *Major Event Organizations*, the International Olympic Committee (IOC) or the International Paralympic Committee (IPC).

refer to its *WADA* accreditation or approval status, respectively, for an activity that falls under Analytical Testing for *Code*-compliant *Anti-Doping Organizations*.

3.4 Sharing of Knowledge

3.4.1 When information on new doping substance(s), method(s), or practice(s) is known to the Laboratory, such information shall be shared with *WADA* within sixty (60) calendar days [76]. When possible, the Laboratories shall share information with *WADA* regarding the detection of potentially new or rarely detected doping agents as soon as possible. Immediately after having been notified of the *Use* of a new substance or method as a doping agent, *WADA* will inform all Laboratories.

3.4.2 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.

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

4.1 The personnel of Laboratories and WADA-Approved Laboratories for the ABP 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.

4.2 All employees of Laboratories and WADA-Approved Laboratories for the ABP shall strictly respect the confidentiality of Analytical Testing results, as well as of all other Laboratory or Testing Authority information, including information provided by *WADA* under confidentiality.

4.3 No employee or consultant of Laboratories and WADA-Approved Laboratories for the ABP shall provide counsel, advice or information to *Athletes* or others regarding techniques or methods used to mask or avoid detection of, alter metabolism of, or suppress excretion of a *Prohibited Substance* or its *Metabolite*(s), or *Marker*(s) of a *Prohibited Substance* or *Prohibited Method* in order to avoid an *Adverse Analytical Finding*.

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

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

[Comment: Arts. 4.3 – 4.5 do not prohibit the publication and/or presentation of scientific research results, general presentations to educate *Athletes*, students, or others concerning anti-doping programs and *Prohibited Substances* or *Prohibited Methods*.]

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

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

4.7 The Laboratory or WADA-Approved Laboratory for the ABP shall not issue any statements related to the Laboratory analytical processes or findings, unless otherwise provided in *Code* Art. 14.3.5. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be the sole responsibility of the responsible *Anti-Doping Organization*(s) or *WADA*.

5.0 Breach and Enforceability

A failure to respect any of the provisions of this Code of Ethics may result in the Laboratory or WADA-Approved Laboratory for the ABP being subject to Disciplinary Proceedings instituted by *WADA* to either suspend or revoke its *WADA* accreditation or its *WADA* approval, as applicable, in accordance with ISL Art. 4.6.4.5.

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

ISL ANNEX B – PROCEDURAL RULES FOR THE DISCIPLINARY COMMITTEE OF THE INTERNATIONAL STANDARD FOR LABORATORIES

Preamble

These Procedural Rules for the Disciplinary Committee (DC) of the ISL (the "Procedural Rules") outline the process to be followed when a Laboratory appeals a recommendation of the LabEG in accordance with ISL Art. 4.6.4.1.2, when a Laboratory is subject to Revocation proceedings in accordance with ISL Art. 4.6.4.3 or, when and where applicable, Disciplinary Proceedings are instituted against a WADA-Approved Laboratory for the ABP in accordance with ISL Art. 4.8.4.1. In such circumstances, any reference made to a Laboratory in these Procedural Rules shall be understood as a reference to a WADA-Approved Laboratory for the ABP, unless such reference is not applicable due to the circumstances, specific nature or rules indicated in this ISL in relation to WADA-Approved Laboratories for the ABP.

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

PART I - Composition of the Committee

Art. 1

For each individual case, a DC shall be constituted. It shall be composed of three (3) members including a Chairperson.

WADA's Director General shall appoint the three (3)-member DC for each case and decide which one will serve as Chairperson.

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

All members of an appointed DC shall be free of any conflict of interest with *WADA*, the Laboratory concerned, or any other Laboratory, entity, organization or individual that could potentially benefit from the concerned Laboratory's Suspension, Revocation or Analytical Testing Restriction, and must otherwise be impartial in relation to *WADA* and the Laboratory concerned. The anti-doping laboratory expert(s) may be member(s) of the *WADA* Laboratory Expert Group (LabEG), unless the case has been the subject of previous discussion or recommendation by the LabEG.

All DC members shall sign a declaration in which they confirm their impartiality and mention any circumstance, which may be relevant in this respect.

Art. 2

If the impartiality of any member of the DC is challenged (for example, by the Laboratory), the matter shall be decided by the Chairperson if he is not the concerned DC member or by the two other DC members if the challenge concerns the Chairperson. In the event the two DC members cannot agree, *WADA*'s Director General shall make the decision.

The decision is not subject to an independent challenge.

PART II - General Provisions

Art. 3

3.1 Once the DC is constituted, *WADA* will provide it with the complete case file, including all of the evidence it wishes to submit in support of the disciplinary action being taken against the Laboratory. *WADA* may send the case file and any information to the DC electronically or by registered mail.

3.2 Simultaneously, *WADA* shall provide the Laboratory with the complete case file and with all of the available supporting evidence. *WADA* may send the case file and any information to the Laboratory electronically or by registered mail.

3.3 Within five (5) business days of receiving the full case file, the Laboratory may respond in writing and provide all of its evidence to the DC and shall also simultaneously provide copies of all its submissions and evidence to *WADA*'s Legal Department. Any requests to extend this deadline shall be addressed by the Laboratory to the Chairperson of the DC, who shall have the discretion to grant or reject the requested extension.

3.4 Upon receipt of the Laboratory's submissions and evidence, *WADA* shall have five (5) business days to make rebuttal submissions to the Disciplinary Committee. Any requests to extend this deadline shall be addressed by *WADA* to the Chairperson of the DC, who shall have the discretion to grant or reject the requested extension.

3.5 If the Laboratory fails or chooses not to respond or provide evidence within the required time frame, the disciplinary proceedings will continue on the basis of the evidence at the disposal of the DC.

Art. 4

Unless both parties agree otherwise or the Chairperson orders otherwise on the basis of exceptional circumstances, the parties shall not be permitted to include additional material after the submission of the final evidence packages in accordance with the procedure described in Art. 3 above.

Art. 5

The working language of the DC shall be English. The DC may accept documents in other languages at its discretion.

PART III - Scope of the Committee's Review

Art. 6

6.1 The DC shall have the authorization to review the evidence of the case and to make a recommendation regarding the status of the Laboratory's *WADA* accreditation.

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

6.3 The DC shall have the right to appoint one or more independent expert(s) should it consider that particular expertise is required in order for it to make its recommendation to maintain, suspend or revoke a Laboratory's *WADA* accreditation or to impose an Analytical Testing Restriction.

6.4 After consulting the parties, the DC may, if it deems itself to be sufficiently well informed, decide not to hold a hearing and it may determine its recommendation based on the parties' written submissions and the available documents.

6.5 The DC shall make its recommendation in accordance with the applicable regulations, including the *Code*, the ISL and any relevant Technical Documents or Technical Letters, or any other rules or law agreed to by *WADA* and the Laboratory, and by default, Swiss law.

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

PART IV - Recommendation

Art. 7

7.1 The recommendation of the DC shall be issued in writing, with reasons [77], within fourteen (14) calendar days of the conclusion of the hearing. If no hearing is held, the DC shall issue its recommendation within fourteen (14) calendar days of the communication to the parties that no hearing will be held.

7.2 Where the DC considers that a Laboratory's accreditation should be suspended or subject to an Analytical Testing Restriction, it shall recommend a period of Suspension or Analytical Testing Restriction that is proportionate to the seriousness of the noncompliance(s) with the ISL and/or Technical Document(s) and/or Technical Letters and the need to ensure accurate and reliable Analytical Testing of *Samples*.

7.3 The DC may recommend to the Chair of the *WADA* Executive Committee that a Laboratory's *WADA* accreditation be suspended or subjected to an Analytical Testing Restriction for a period of up to six (6) months (with one possible extension of up to six (6) months). During this time, any ISL and/or Technical Document and/or Technical Letter noncompliance(s) identified within the context of the Disciplinary Proceedings instituted against the Laboratory and resulting in the Suspension of its *WADA* accreditation or the imposition of an Analytical Testing Restriction, or during a subsequent on-site assessment conducted by *WADA* during the Laboratory's Suspension or during the period of the Analytical Testing Restriction, shall be corrected, documented, reported to *WADA* and determined to be satisfactory by *WADA.* The DC shall also indicate any conditions that the Laboratory shall satisfy prior to the reinstatement of the Laboratory's *WADA* accreditation.

7.4 In cases where it considers that it is appropriate to do so, the DC may also recommend that the Laboratory receive a warning with no period of Suspension or no imposition of an Analytical Testing Restriction.

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

7.6 If the DC recommends the Suspension of the Laboratory's *WADA* accreditation or the imposition of an Analytical Testing Restriction, the Chair of the *WADA* Executive Committee shall render a final

[77] The decision may be summarily reasoned.

decision regarding the Suspension of the Laboratory's *WADA* accreditation or the imposition of an Analytical Testing Restriction within ten (10) calendar days of receiving the DC's recommendation.

7.7 If the DC recommends the Revocation of the Laboratory's *WADA* accreditation, the *WADA* Executive Committee shall render a decision regarding the Revocation of the Laboratory's *WADA* accreditation within ten (10) calendar days of receiving the DC's recommendation.

7.8 If the DC recommends that the Laboratory shall maintain its *WADA* accreditation, the Laboratory shall be informed accordingly by *WADA* within seven (7) calendar days of receiving the DC's recommendation.