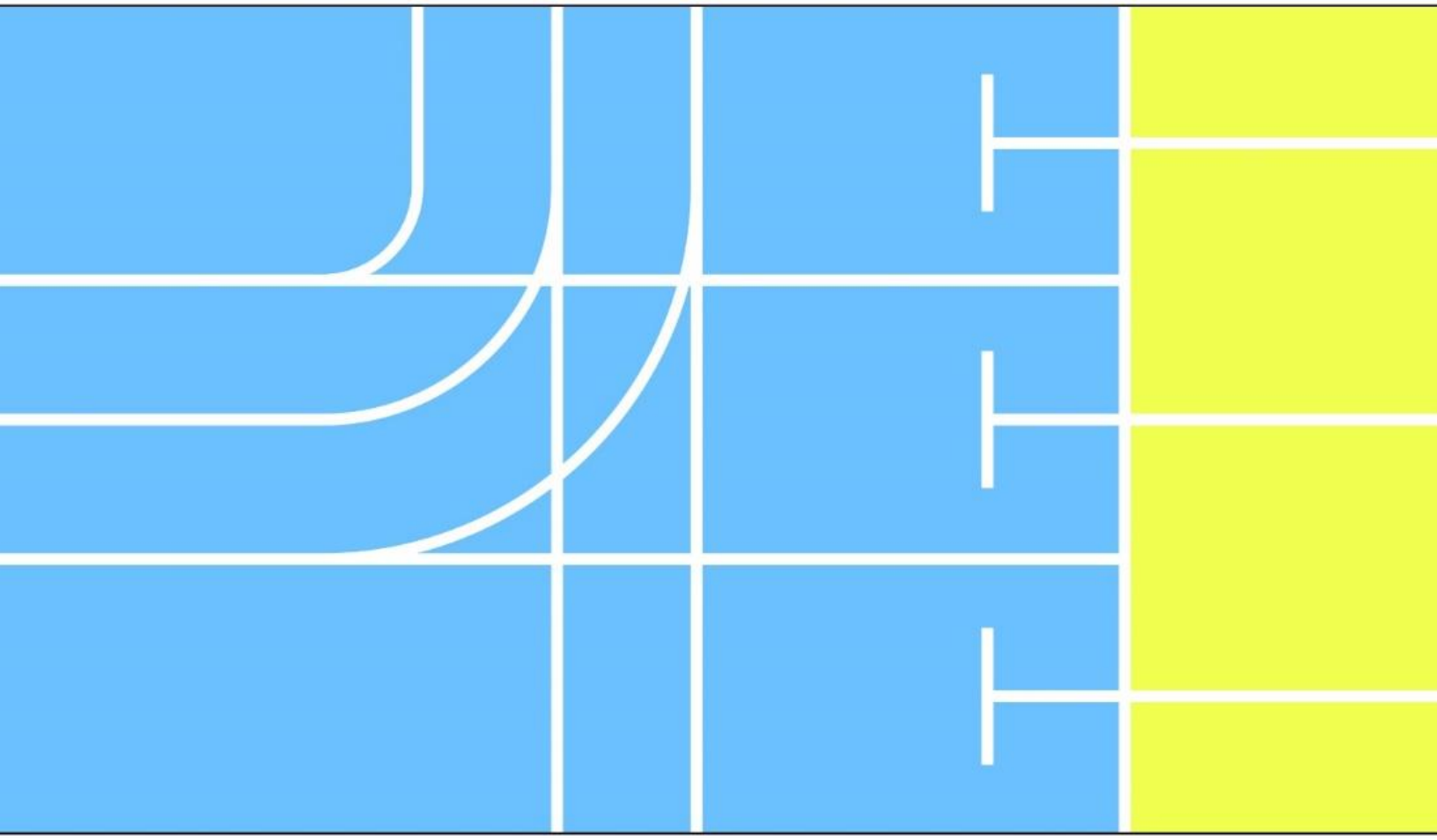
wada

World Anti-Doping Code

# International Standard for Laboratories



2027

## *International Standard* for Laboratories

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

The *International Standard* for Laboratories first came into effect in November 2002. It was subsequently amended multiple times, specifically in 2003, 2004, 2008, 2009, 2012, 2015, 2016, 2019 and 2021. A revised version was approved by the *WADA* Executive Committee on 5 December 2025 and is effective as of 1 January 2027.

Published by:

World Anti-Doping Agency
Stock Exchange Tower
800 Place Victoria (Suite 1700)
PO Box 120
Montreal, Quebec Canada
H3C 0B4

www.wada-ama.org

Tel: +1 514 904 9232
Fax: +1 514 904 8650
E-mail: code@wada-ama.org

# Table of Contents

# PART ONE: INTRODUCTION, *CODE* PROVISIONS, DEFINITIONS, TECHNICAL DOCUMENTS, AND INTERPRETATIONS

## 1.0 Introduction and Scope

### 1.1 *WADA* Laboratory Standards

#### 1.1.1 *International Standard* for Laboratories (ISL)

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

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

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

The ISL sets out the requirements to be followed by Laboratories and *ABP* Laboratories to ensure that they are technically competent, operate within an effective Management System, and are able to produce valid analytical results. The ISL includes, *inter alia*, a description of the *WADA* accreditation and *ABP* approval processes, including the requirements for obtaining and maintaining *WADA* Laboratory accreditation and *WADA ABP* Laboratory approval, as well as operating standards for the performance of Laboratories and *ABP* Laboratories. The ISL also sets out requirements and guidance for *ADO*s in relation to *Sample* custody and storage, Analytical *Testing* and some aspects of *Results Management*.

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

### 1.1.2 *Technical Documents* (*TD*s)

*TD*s are issued by *WADA* to provide comprehensive instructions to the Laboratories, *ABP* Laboratories and other W*ADA* stakeholders on analytical or procedural issues. *TDs* are modified and/or withdrawn by *WADA* as appropriate.

a) Approval and Publication of *TD*s

i. In the case that the implementation of a new or revised *TD* is not time sensitive, a stakeholder consultation (including Laboratories and *ABP* Laboratories, if applicable) will be conducted for new or revised *TD* drafts. The stakeholder consultation may not be needed if a revised *TD* includes just minor, low-impact modifications (e.g., correction of typographical errors, formatting changes).

ii. Final versions of *TD*s are approved by the *WADA* Executive Committee and published on *WADA's* website.

b) Implementation of *TD*s

i. Once approved and published, a *TD* becomes an integral part of the ISL and supersedes any previous publication on a similar topic[1], including *TL*s and/or the ISL.

ii. The implementation of the requirements detailed in an approved and published *TD* may occur prior to the effective date for implementation specified in the *TD* and shall occur no later than the effective date (deadline for implementation).

iii. A failure by a Laboratory or *ABP* Laboratory to implement a *TD* by the effective date may result in the imposition of an ATR against the Laboratory for that particular Analytical *Testing* Procedure or for the analysis of that particular class of *Prohibited Substances* or *Prohibited Methods*, or a Suspension of the Laboratory's *WADA* accreditation, or a Suspension of the approval for the *ABP*, respectively, as determined by *WADA*.

*[Comment to Article 1.1.2b): The effective date for implementation of a TD shall be interpreted as the deadline, following approval and publication of the TD, by which the TD shall be implemented by Laboratories and/or ABP Laboratories. However, Laboratories and ABP Laboratories may implement a TD as soon as it is approved by the WADA Executive Committee and published on WADA's website, provided that the requirements of the TD have been implemented and documented in the Laboratory's or ABP Laboratory's Management System. If a Laboratory or ABP Laboratory is not able to implement a new TD by its effective date, it shall inform its clients and WADA as soon as possible. The Laboratory or ABP Laboratory shall send a written request to WADA for an extension beyond the applicable effective date, providing the reason(s) for the delayed implementation of the TD, any measures taken to ensure that Samples received in the Laboratory or ABP Laboratory will be subject to Analytical Testing in compliance with the new TD (for example, by*

[1] *WADA* will provide guidance to Laboratories, *ABP* Laboratories and other *WADA* stakeholders on the standard(s) that may be affected by a new or revised *TD* or *TL* in the Summary of Modifications that accompanies the publication of the approved version of the *TD* or *TL*.

*subcontracting the analysis to another Laboratory or ABP Laboratory, as applicable), as well as plans for the implementation of the new TD.]*

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

c) Application of *TD*s

i. When a newly approved version of a *TD* lowers either a *DL* for a Threshold Substance or an *MRL* for a Non-Threshold Substance, as applicable, the revised limits specified in the new *TD* shall not be applied to the reporting of analytical results for *Samples* collected before the effective date of the *TD,* even if the Laboratory or *ABP* Laboratory already implemented and documented the requirements of the new *TD* in their Management System before the effective date.

*[Comment to Article 1.1.2c): For example, if the application of a newly approved TD would result in an AAF for a Sample with a collection date prior to the effective date of that new TD, which would not have resulted in an AAF with the application of the currently effective version of the TD in effect at the time of Sample collection (for example if the DL for a Threshold Substance has been lowered in the newly approved TD), 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.]*

ii. The most recently approved *TD* shall be applied to the Analytical *Testing* of *Samples* prior to the effective date if it would lead to a result that benefits the *Athlete* (e.g., increase of the *DL* for a Threshold Substance or of the *MRL* for a Non-Threshold Substance, establishment of more stringent identification criteria for chromatographic-mass spectrometric or electrophoretic CP). Therefore, in the case where an analytical finding does not meet the reporting criteria defined in the new *TD*, it shall be reported as a Negative Finding.

iii. Subject to the above, the analysis of *Samples* or the review of Analytical Data may occur immediately once a *TD* has been approved and the Laboratory or *ABP* Laboratory has implemented and documented the requirements of the new *TD* in their Management System.

### 1.1.3 *Technical Letters* (*TL*s)

*TL*s are issued on an *ad hoc* basis to provide instructions to the Laboratories and other stakeholders on particular issues on the analysis, interpretation and reporting of results for specific *Prohibited Substance*(s) and/or *Prohibited Method*(s) or on the application of specific Laboratory procedures. *TL*s are amended and/or withdrawn by *WADA* as appropriate.

a) Approval and Publication of *TL*s

i. In the case that the implementation of a new or revised *TL* is not time sensitive, a stakeholder consultation (including Laboratories) will be

conducted for new or revised *TL* drafts. The stakeholder consultation may not be needed if a revised *TL* includes just minor, low-impact modifications (e.g., correction of typographical errors, formatting changes).

ii. Final versions of *TL*s are published on *WADA*'*s* website after approval by the *WADA* Executive Committee and become effective immediately, unless otherwise specified by *WADA*.

*[Comment to Article 1.1.3a): TLs may require actions (e.g. validation of new Analytes or modifications to Analytical Testing Procedures, the procurement of RMs or RCs), 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 TL.]*

b) Application of *TL*s

i. Once approved, a *TL* becomes an integral part of the ISL and supersedes any previous publication on a similar topic[1], including *TD*s and/or the ISL.

ii. A failure by a Laboratory to implement a *TL* by the effective date may result in the imposition of an ATR against the Laboratory for that particular Analytical *Testing* Procedure or for the analysis of that particular class of *Prohibited Substances* or *Prohibited Methods*, or a Suspension of the Laboratory's *WADA* accreditation, as determined by *WADA*.

iii. The implementation of the requirements of relevant *TL*s into the Laboratory's Management System is mandatory for obtaining and maintaining *WADA* accreditation or approval, respectively, and for the application of the relevant Analytical *Testing* Procedure(s) to the analysis of *Samples.*

### 1.1.4 Laboratory Guidelines (LGs)

LGs are issued to provide guidance to the Laboratories and other *WADA* stakeholders on new Analytical Methods or procedures approved by *WADA*. LGs are modified and/or withdrawn by *WADA*, as appropriate.

a) Approval and Publication of LGs

i. LGs may be consulted with *WADA* stakeholders (including Laboratories).

ii. Final versions of LGs are published on *WADA*'*s* website after approval by the Lab EAG and become effective immediately, unless otherwise specified by *WADA*.

b) Application of LGs

The application of LGs is not mandatory. However, Laboratories are encouraged to follow, to the fullest extent possible, the recommendations of best practice included in relevant LGs.

### 1.1.5 Technical Notes (TNs)

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

a) Approval of TNs

i. TNs are not subject to a consultation with *WADA* stakeholders.

ii. TNs are approved by the Lab EAG.

iii. TNs are provided on a confidential basis to Laboratories only and are not published on *WADA*'s website.

b) Application of TNs

The application of the recommendations detailed in TNs is not mandatory. However, Laboratories are encouraged to follow, to the fullest extent possible, the technical guidance included in TNs.

## 1.2 *Sample* Analysis

*Sample* analysis is part of the Analytical *Testing* process and involves the detection, identification, and in some cases demonstration of the presence above a Threshold or of the exogenous origin 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 and *ABP* Laboratories may accept samples for other forms of analysis, subject to the *provisions* of the ISL Code of Ethics (see Section 8.0), which are not under the scope of *WADA* accreditation or *ABP* approval (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 or *ABP* approval and, therefore, shall not be subject to the requirements of the ISL, *TD*s or *TL*s. For the avoidance of doubt, Test Reports or other documentation or correspondence from Laboratories or *ABP* Laboratories shall not declare or represent that any such testing is covered under their *WADA* accreditation or *ABP* approval status.

## 1.3 *WADA* Laboratory Accreditation Framework and *ABP* Laboratory Approval

The *WADA* Laboratory accreditation and *ABP* Laboratory approval framework consists of two (2) main elements: Part Two of the ISL (Laboratory accreditation and *ABP* Laboratory approval requirements and operating standards) and Part Three (the Annexes).

a) Part Two of the ISL describes the requirements necessary to obtain and maintain *WADA* accreditation and the procedures involved to fulfill these requirements, as well as the requirements necessary to obtain and maintain *WADA* approval for the *ABP*, as well as the specific requirements to conduct Analytical *Testing* during Major *Events* (Section 4.0). It also includes the application of ISO/IEC 17025 [2] to the field of *Doping Control* (Section 5.0), a brief description of the *WADA* Laboratory and *ABP* Laboratory

[2] Effective version of ISO/IEC 17025.

monitoring and performance evaluation activities (Section 6.0) as well as the Laboratory and *ABP* Laboratory disciplinary procedures (Section 7.0) and the ISL Code of Ethics (Section 8.0). The purpose of Part Two of the ISL is to enable the consistent application of ISO/IEC 17025 and ISL-specific requirements to Analytical *Testing* for *Doping Control* by Laboratories and *ABP* Laboratories, as well as to facilitate the assessment of Laboratory and *ABP* Laboratory compliance by Accreditation Bodies and *WADA.*

b) Part Three of the ISL includes the Annex A (Procedural Rules), which describes the procedural rules for the Disciplinary Committee (DC) of the ISL.

In order to harmonize the accreditation of Laboratories to the requirements of ISO/IEC 17025 and the approval of *ABP* Laboratories to the requirements of ISO/IEC 17025 (or ISO 15189), as well as the *WADA*-specific requirements for accreditation or approval, Accreditation Bodies are required to use the ISL, *TD*s, *TL*s and LGs as reference documents in their assessment process.

*[Comment to Article 1.3: While Laboratories are required to be accredited to the requirements of ISO/IEC 17025 (applicable to testing and calibration laboratories), ABP Laboratories may be accredited to either the ISO/IEC 17025 or ISO 15189 (applicable to medical laboratories) standards].*

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

## 2.0 *Code* Provisions

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

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

## 3.0 Definitions and Interpretations

### 3.1 Defined terms from the 2027 *Code* that are used in the *International Standard* for Laboratories

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

***Adverse Analytical Finding* (*AAF*):** A report from a *WADA*-accredited laboratory or other *WADA*-approved laboratory that, consistent with the *International Standard* for Laboratories establishes in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* or evidence of the *Use* of a *Prohibited Method*.

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

***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 *NADO).* An *ADO* 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 *ADO* 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 *ADO* has elected to exercise its authority to test and who competes below the international or national level, then the *Consequences* set forth in the *Code* must be applied. For purposes of Article 2.8 and Article 2.9 and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

*[Comment to Athlete: Individuals who participate in sport may fall in one of five categories: 1) International-Level Athlete, 2) National-Level Athlete, 3) individuals who are not International or National-Level Athletes but over whom the International Federation or NADO has chosen to exercise authority, 4) Recreational Athlete, and 5) individuals over whom no International Federation or NADO has, or has chosen to, exercise authority. All International and National-Level Athletes are subject to the anti-doping rules of the Code, with the precise definitions of international and national level sport to be set forth in the anti-doping rules of the International Federations and NADOs.]*

***Athlete Biological Passport* (*ABP*):** The program and methods of gathering and collating data as described in the *International Standard* for *Testing* and *International Standard* for Laboratories.

***Atypical Finding* (*ATF*):** A report from a *WADA*-accredited laboratory or other *WADA*-approved laboratory, which requires further investigation as provided by the applicable *International Standards* (including related *Technical Documents* or *Technical Letters*),

*WADA* stakeholder notice, or as directed by *WADA*, prior to the final determination about the finding (i.e., the establishing, or not, of an anti-doping rule violation).

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

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

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

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

***Decision Limit* (*DL*):** The value above which a quantitative analytical result for a Threshold Substance in a *Sample* shall be reported as an *Adverse Analytical Finding.*

*[Comment to Decision Limit: For more information on DLs and which Threshold Substances they are applied for, refer to the TD DL and other applicable Technical Documents (e.g., TD GH, TD CG/LH).]*

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

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

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

***In-Competition* (*IC*):** The period commencing at 11: 59 pm on the day before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*. Provided, however, *WADA* may approve, for a particular sport, an alternative definition if an International Federation provides a compelling justification that a different definition is necessary for its sport; upon such approval by *WADA*, the alternative definition shall be followed by all *Major Event Organizations* for that particular sport.

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

***Ineligibility*:** See *Consequences of Anti-Doping Rule Violations* above.

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

***Major Event Organization* (*MEO*):** A continental association of *National Olympic Committees* and other international multi-sport organizations that function as the ruling body for any continental, regional or other *International Event*.

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

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

***Minimum Reporting Level* (*MRL*):** Value below which an estimated analytical result for some Non-Threshold Substances should not be reported as an *Adverse Analytical Finding*.

*[Comment to Minimum Reporting Level: For more information on Minimum Reporting Levels and the Non-Threshold Substances to which they shall be applied, refer to the TD MRPL.]*

***National Anti-Doping Organization* (*NADO*):** 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 *NOC* or its designee.

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

***Out-of-Competition* (*OOC*):** 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*.

***Quality Assurance*:** Processes aimed at maintaining and improving the quality of Analytical *Testing* Procedures (as further defined in the *International Standard* for Laboratories), i.e., quality control, quality improvement, method development and validation, generation and evaluation of reference population data, analysis of substances included in the *WADA* monitoring program as described in *Code* Article 4.5, and any other legitimate *Quality Assurance* process, as determined by *WADA*, aimed at monitoring the validity of Analytical *Testing* Procedures applied to the analysis of *Prohibited Substances* and *Prohibited Methods* for the purposes established in *Code* Article 6.2.

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

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

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

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

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

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

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

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

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

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

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

***WADA*:** The World Anti-Doping Agency.

## 3.2 Defined Terms from the *International Standard* for Laboratories

***ABP* Laboratory:** A laboratory not otherwise accredited by *WADA,* which is approved by the *WADA* Executive Committee to apply Analytical Methods and processes in support of the Hematological Module of the *ABP* program.

*[Comment to ABP Laboratory: To facilitate the comprehension and interpretation of ISL provisions, when requirements apply to both Laboratories and ABP Laboratories, both will be referred to as "Laboratory(-ies)". If, instead, provisions apply exclusively to either Laboratories or ABP Laboratories, the specific definition will be used as applicable.*

*Instead, when the term "laboratory" is used, it implies laboratories that are neither WADA-accredited nor ABP approved, which may be involved in analytical areas other than anti-doping.]*

**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* or degradation product of a *Prohibited Substance*, or a *Marker* of the *Use* of a *Prohibited Substance* or *Prohibited Method*.

**Analytical Method:** Analytical *Testing* Procedures and Test Methods.

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

**Analytical *Testing* Procedure:** A Fit-for-Purpose procedure, as demonstrated through method validation, and used to detect, identify and/or quantify Analytes in a *Sample* for *Doping Control* purposes in accordance with the ISL and relevant *TD*s*, TL*s or LGs. An Analytical *Testing* Procedure is also referred to or known as an Analytical Method or Test Method.

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

**Applicant *ABP* Laboratory**: Laboratory applying to become a Candidate *ABP* laboratory for *WADA* approval for the *ABP*.

**Applicant Laboratory**: Laboratory applying to become a Candidate laboratory for *WADA* accreditation.

***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.

**Candidate Laboratory:** Laboratory in the candidate phase of *WADA* accreditation, as approved by the *WADA* Executive Committee.

**Candidate *ABP* Laboratory:** Laboratory in the candidate phase of *WADA* approval for the *ABP*, as approved by the *WADA* Executive Committee.

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

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

**Confirmation Procedure (CP):** An Analytical *Testing* Procedure that has the purpose of confirming the presence and/or, when applicable, determining the quantitative value (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) and/or establishing the origin (exogenous or endogenous) of one or more specific Analytes.

**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 Analytes. The EQAS includes also the provision of blood *Samples* to *ABP* Laboratories for the analysis of the blood *Markers* of the *ABP*. 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 *TD*s and *TL*s.

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

*[Comment to Flexible Scope of ISO/IEC 17025 Accreditation: The concept of flexible scope of accreditation may also be applied, as determined by the Accreditation Body, to the analysis of ABP blood Markers when included in the scope of ISO 15189 accreditation of ABP Laboratories.]*

**Further Analysis:** Further Analysis, as this term is used in the ISL, occurs when a Laboratory conducts additional analysis on an "A" *Sample* or a "B" *Sample* after an

analytical result for that "A" *Sample* or that "B" *Sample* has been reported by the Laboratory.

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

*If a Laboratory is to conduct additional analysis on an "A" Sample or "B" Sample after an analytical result for that Sample has been reported (for example: additional Sample analysis to detect EPO, or GC/C/IRMS analysis, or analysis in connection with the ABP or additional analysis on a stored Sample) it may do so after receiving approval from the TA or RMA (if different) or WADA. However, after an Athlete has been charged with a Code Article 2.1 anti-doping rule violation and the case has not been finally resolved, then Further Analysis on that Sample may only be performed with the consent of the Athlete or approval from a hearing body (see Code Article 6.5).*

*Further Analysis may be performed by the same Laboratory that did the original Analytical Testing, or by a different Laboratory or other WADA-approved laboratory, at the direction of the TA or RMA (if different) or WADA. Any other ADO that wishes to conduct Further Analysis on a stored Sample may do so with the permission of the TA or RMA (if different) or WADA and shall be responsible for any follow-up Results Management. Any Sample storage or Further Analysis initiated by WADA, or another ADO shall be at WADA's or that ADO's expense.]*

**Independent Witness:** A *Person*, invited by the TA, the Laboratory or *WADA* to witness the opening and initial aliquoting of an *Athlete's* "B" *Sample*. An Independent Witness shall not be an employee or have a personal financial relationship with the *Athlete* or his/her representative(s), the Laboratory, the SCA, the TA / *DTP* / RMA or *WADA*, as applicable. However, the Independent Witness may be indemnified for his/her service.

**Initial *Testing* Procedure (ITP):** An Analytical *Testing* Procedure whose purpose is to identify those *Samples* which may contain an Analyte or an elevated quantity of an Analyte.

**Laboratory:** A *WADA*-accredited laboratory, as approved by the *WADA* Executive Committee.

*[Comment to Laboratory: To facilitate the comprehension and interpretation of ISL provisions, when requirements apply to both Laboratories and ABP Laboratories, both will be referred to as "Laboratory(-ies)". If, instead, provisions apply exclusively to either Laboratories or ABP Laboratories, the specific definition will be used as applicable.*

*Instead, when the term "laboratory" is used, it implies laboratories that are neither WADA-accredited nor ABP approved, which may be involved in analytical areas other than anti-doping.]*

**Laboratory Documentation Package (LDOC):** The material produced by a Laboratory upon request by the TA, RMA or *WADA*, as set forth in the *TD* on Laboratory Documentation Packages (*TD* LDOC), to support an analytical result such as an *AAF* or an *ATF*.

*[Comment to Laboratory Documentation Package: Laboratories and ABP Laboratories may also produce ABP LDOCs, if requested by the TA, RMA, Passport Custodian, APMU or WADA to support the compilation of an ABP Documentation Package.]*

**Laboratory Expert Advisory Group (Lab EAG):** Group of laboratory experts responsible for providing advice and recommendations to *WADA* with respect to the overall management of anti-doping laboratory accreditation and *ABP* approval processes, the

production of Laboratory normative documents, and the conduct of Laboratory and *ABP* Laboratory monitoring activities and disciplinary procedures.

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

*[Comment to Laboratory Guidelines: LGs may be later incorporated, partially or in full, in TDs or in the ISL.]*

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

*[Comment to Laboratory Internal Chain of Custody: LCOC 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.]*

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

*[Comment to Limit of Detection: When using chromatographic-mass spectrometric Analytical Methods, the LOD is expressed as the minimum concentration of the Analyte that can be routinely detected (but not necessarily identified or quantified) in representative samples at a 95% detection rate.]*

**Limit of Identification (LOI):** Analytical parameter of technical performance for chromatographic-mass spectrometric CPs. For a given Analyte (for which an RM is available), the LOI of a Test Method shall be determined at 95% identification rate and shall be less than the corresponding MRPL.

*[Comment to Limit of Identification: Since the LOI is an estimation of the identification rate at 95% probability obtained by the Laboratory during Test Method validation, the Laboratory may report a finding below the validated LOI as AAF or ATF, as applicable, when the Analyte is identified in the Sample according to the criteria established in the TD on Chromatographic-Mass Spectrometric Identification Criteria (TD IDCR).]*

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

**Major *Event*:** A series of individual international competitions conducted together under an international multi-sport organization functioning as a ruling body (e.g., the Olympic Games, Pan American Games).

**Measurement Uncertainty (MU):** Non-negative parameter associated with a measurement result that characterizes the dispersion of values obtained with the measurement procedure (see *TD* on *DLs* (*TD DL*)).

**Minimum Required Performance Level (MRPL):** Minimum analytical requirement of Laboratory technical performance established by *WADA*. Minimum concentration at which a Laboratory is expected to consistently detect and confirm an Analyte in the routine daily

operation of the Laboratory. Individual Laboratories may and are expected to achieve better performance (see *TD* on MRPL (*TD* MRPL)).

**Negative Finding:** A test result from a Laboratory which, in accordance with the effective ISL and/or relevant *TD*s and/or *TL*s, concludes that no Analyte included in the requested Analytical *Testing* menu was found in a *Sample* based on the applied ITPs or CPs.

**Non-Threshold Substance:** A *Prohibited Substance* for which a Threshold has not been established and for which, therefore, the identification of an Analyte of the *Prohibited Substance* in a *Sample* constitutes an *AAF*. Some Non-Threshold Substances have an associated *MRL.*

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

**Probationary Laboratory:** Laboratory in the probationary phase of *WADA* accreditation, as approved by the Lab EAG.

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

**Reference Collection (RC):** A *Sample(s)* of known origin that may be used in the determination of the identity of a substance. For example, a well-characterized *Sample* obtained from a controlled administration, from *in vitro* studies or from past *Doping Controls* 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.

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

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

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

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

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

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

**Threshold:** The maximum permissible level (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) for a Threshold Substance in a *Sample*. The Threshold is used to establish the *DL* for reporting an *AAF* or *ATF* for a Threshold Substance.

**Threshold Substance:** A *Prohibited Substance* for which the identification and quantitative determination (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) of an Analyte in excess of a pre-determined *DL*, or, when applicable, the establishment of an exogenous origin, constitutes an *AAF*. Threshold Substances are identified as such in the *TD* on *DLs* (*TD DL*) and other applicable *TD*s.

## 3.3 Defined Terms from the *International Standard* for *Testing*

***Sample* Collection Authority (SCA):** The organization that is responsible for the collection of *Samples* in compliance with the requirements of the *International Standard* for *Testing*, whether (1) the TA itself; or (2) a *DTP* to whom the authority to conduct *Testing* has been granted or sub-contracted. The TA always remains ultimately responsible under the *Code* for compliance with the requirements of the *International Standard* for *Testing* relating to collection of *Samples*.

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

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

**Test Distribution Plan (TDP):** A document written by an *ADO* that plans *Testing* on *Athletes* over whom it has TA, in accordance with the requirements of Article 4.7 of the *International Standard* for *Testing*.

***Testing* Authority (TA):** The *ADO* that authorizes *Testing* on *Athletes* it has authority over. It may authorize a *DTP* to conduct *Testing* pursuant to the authority of and in accordance with the rules of the *ADO.* Such authorization shall be documented. The *ADO* authorizing *Testing* remains the TA and ultimately responsible under the *Code* to ensure the *DTP* conducting the *Testing* does so in compliance with the requirements of the *International Standard* for *Testing*.

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

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

**Passport Custodian:** The *ADO* responsible for *Result Management* of the *Athlete*'s Passport and for sharing any relevant information associated to that *Athlete*'s Passport with other *ADO*s.

***Results Management* Authority (RMA):** The *ADO* responsible for conducting *Results Management* in a given case.

## 3.5 *Technical Documents* cited in this *International Standard* for Laboratories

a) *TD* BAR – Analytical Requirements for the Hematological Module of the *Athlete Biological Passport*.

b) *TD* CG/LH – Analysis, Reporting & Management of Urinary Human Chorionic Gonadotrophin (hCG) and Luteinizing Hormone (LH) Findings in Male *Athletes*.

c) *TD* DBS – Dried Blood Spots (DBS) for *Doping Control*. Requirements and Procedures for Collection, Transport, Analytical *Testing* and Storage.

d) *TD DL – Decision Limits* for the Confirmatory Quantification of Exogenous Threshold Substances by Chromatography-based Analytical Methods.

e) *TD* EAAS – Measurement and Reporting of Endogenous Anabolic Androgenic Steroid (EAAS) *Markers* of the Urinary Steroid Profile.

f) *TD* EPO – Harmonization of Analysis and Reporting of Erythropoietin (EPO)-Receptor Agonists (ERAs) and Transforming Growth Factor-beta (TGF-β) Signalling Inhibitors by Polyacrylamide Gel Electrophoretic (PAGE) Analytical Methods.

g) *TD* EQAS – External Quality Assessment Scheme.

h) *TD* GH – Human Growth Hormone (hGH) Isoform Differential Immunoassays for *Doping Control* Analyses.

i) *TD* IDCR – Minimum Criteria for Chromatographic-Mass Spectrometric Confirmation of the Identity of Analytes for *Doping Control* Purposes.

j) *TD* IRMS – Detection of Synthetic Forms of *Prohibited Substances* by GC/C/IRMS.

k) *TD* LCOC – Laboratory Internal Chain of Custody.

l) *TD* LDOC – Laboratory Documentation Package.

m) *TD* MRPL – Minimum Required Performance Levels and Applicable *Minimum Reporting Levels* for Non-Threshold Substances Analyzed by Chromatographic-Mass Spectrometric Analytical Methods.

n) *TD* PERF – Laboratory Performance Evaluation System.

o) *TD* SSA – Sport Specific Analysis.

p) *TD* VAL – Method Validation.

## 3.6 Interpretation

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

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

c) Like the *Code*, the ISL has been drafted giving consideration to the principles of proportionality, human rights, and other applicable legal principles. It shall be interpreted and applied in that light.

d) The comments annotating various provisions of the ISL shall be used to guide its interpretation.

e) Unless otherwise specified, references to Articles are references to Articles of the ISL.

f) The *TD*s and *TL*s associated with the ISL have the same mandatory status as the rest of the *International Standard* and constitute an integral part of it.

g) The Annexes to the ISL have the same mandatory status as the rest of the *International Standard*.

h) Where the term “days” is used in the ISL, it shall mean calendar days unless otherwise specified.

i) The following terms used in the ISL shall be interpreted as indicated:

- "Shall" to indicate a mandatory requirement;
- "Should" for a recommendation;
- "May" for a permission;
- "Can" for a possibility/capability.

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

## 4.0 Process and Requirements for *WADA* Laboratory Accreditation, *ABP* Laboratory Approval and Laboratory Accreditation for Major *Events*

### 4.1 *WADA* Laboratory Accreditation

#### 4.1.1 Applicant Laboratory for *WADA* Accreditation

In principle, any laboratory that satisfies the criteria listed below may apply to become a Candidate Laboratory for *WADA* accreditation. However, the *WADA* Executive Committee, at its sole discretion, may accept or deny a laboratory's 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).

##### 4.1.1.1 Expression of Interest

The Applicant Laboratory shall officially contact *WADA* in writing to express its interest in becoming a *WADA*-accredited laboratory. At this stage, *WADA* may provide clarifications to the laboratory on the *WADA* accreditation process, including advise on the initial accreditation fee to be paid once the laboratory is approved by the *WADA* Executive Committee as a Candidate Laboratory (see Article 4.1.2.1).

##### 4.1.1.2 Submit Initial Application Form

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

An Applicant Laboratory may only submit an application if its host country satisfies the following conditions:

a) The existence of a robust National Anti-Doping Program conducted by a *NADO* and/or a *RADO*, which is compliant with the *Code* and the *International Standards* of the World Anti-Doping Program.

*[Comment to Article 4.1.1.2 a): The National Anti-Doping Program in the host country of the Applicant Laboratory shall have demonstrated, in the most recent full year, that its Sample collection activities included the collection of at least 3,000 Samples (e.g., urine, blood, blood ABP and Dried Blood Spot (DBS) Samples), of which at least 2,500 shall be urine Samples, which were conducted in compliance with the International Standard for Testing (IST) and the TD SSA, as determined by WADA, and analyzed in a Laboratory(-ies).*

*The host country's National Anti-Doping Program will be evaluated regarding their TDP, Sample collection and Results Management activities.]*

b) The ratification of the UNESCO Convention against Doping in Sport; and

c) The payment of the annual financial contributions to *WADA*.

These conditions shall be confirmed by *WADA* and documented as part of the application.

#### 4.1.1.3 Provision of Letters of Support

The Applicant Laboratory shall submit the following letters of support with their application:

a) Official letter(s) of support from the laboratory's host organization(s), which is acceptable to *WADA* (*e.g.*, universities, hospitals, private organizations and/or public institutions). The letter(s) of support shall 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 and research and development (R&D) activities.

b) Official letter(s) of support from *Signatories*, e.g., *NADO*s or *RADO*s responsible for National Anti-Doping Program(s), International Federation(s) responsible for International Anti-Doping Program(s), *DTP*s in charge of *Doping Control* activities on behalf of *ADO*s. The letter(s) of support shall indicate a commitment to provide the Laboratory with a minimum total of 3,000 *Samples* (including urine, blood, *ABP* blood and DBS *Samples*) per year, of which at least 2,500 shall be urine *Samples,* by the end of the first full calendar year after obtaining *WADA* accreditation.

*[Comment to Article 4.1.1.3 b): To determine the minimum number of Samples, each urine Sample, blood Sample, ABP blood Sample and DBS Sample analyzed by the Laboratory shall count as an individual Sample.]*

c) A declaration by the supporting *Signatory*(-ies) that their relationship with the Applicant Laboratory is compliant with Article 4.1.4.2.5.

#### 4.1.1.4 Provision of Business Plan

The Applicant Laboratory shall submit a business plan, upon request by *WADA,* which shall include market considerations (clients, number of *Samples*, maintenance costs, etc.), facility, instrumental, staffing and training needs, and guarantees for the long-term provision (minimum of three (3) years) of adequate financial and human resources to the laboratory. The business plan shall be provided by the Applicant Laboratory within eight (8) weeks of *WADA*'s request.

### 4.1.2 Candidate Laboratory for *WADA* Accreditation

The application materials described in Articles 4.1.1.1 to 4.1.1.4 shall be evaluated by *WADA*. If *WADA*, upon advice by the Lab EAG, determines that the Applicant Laboratory has satisfactorily met the criteria of Article 4.1, a recommendation will be forwarded to the *WADA* Executive Committee which will determine whether the 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.

#### 4.1.2.1 Payment of Initial Accreditation Fee

Once approved by the *WADA* Executive Committee, the Candidate Laboratory shall pay a one-time non-refundable fee to *WADA* to cover the costs related to the initial accreditation process, including the review of documentation and any necessary follow ups, as well as the preparation, characterization, and shipment of the EQAS *Samples* necessary for the Pre-Probationary Test (PPT) – see Article 4.1.2.6. This fee shall be determined by *WADA* and will be specified in the Initial Application Form.

#### 4.1.2.2 Candidate Laboratory Administrative and Technical Capabilities

Once approved by the *WADA* Executive Committee, the Candidate Laboratory shall complete a detailed questionnaire provided by *WADA* regarding the status of their administrative and technical capabilities and submit it to *WADA* within eight (8) weeks following receipt. The questionnaire will include, but is not limited to, the following information:

a) Staff list and their qualifications.

b) Description of the laboratory facilities and physical security (see Article 5.2.3.1).

c) Description of the laboratory Information Technology (IT) infrastructure and security ((see Article 5.2.3.5).

d) List of actual and proposed instrumental resources and equipment.

e) Status and details of their Analytical *Testing* Procedures:

   i. Status of validated ITPs and CPs, including target Analytes and LODs, LOIs and, where applicable, LOQs and MUs.

   ii. Status of method development and validation, including, at minimum, Validation Reports for all mandatory Analytical Methods (if completed).

   iii. Status of available RMs and RCs and plans for acquisition.

f) List of laboratory sponsors.

g) Contract or Memorandum of Understanding with one or more Laboratory(-ies), which will provide mentoring and training for at least the period spanning the probationary phase of accreditation.

*[Comment to Article 4.1.2.2 g): Candidate Laboratories are encouraged to establish agreement(s) with a Laboratory(-ies) for mentoring and training, at least, up to the end of the probationary phase of accreditation to ensure successful preparation towards obtaining the WADA accreditation.*

*A Candidate Laboratory shall obtain authorization from WADA to receive sensitive anti-doping information (e.g., methodological or technological information, TNs) and/or to specific, WADA-developed anti-doping tests or materials (e.g., kits, RMs). WADA will approve such authorizations on a case-by-case basis according to the Candidate Laboratory's documented roadmap, business plan and the progress made during the accreditation process and shall be subject to the Candidate Laboratory entering into a confidentiality agreement with WADA and/or the mentoring Laboratory(-ies) that will provide the information and/or access to the aforementioned tests and materials.]*

h) Status of ISO/IEC 17025 accreditation.

i) Description of customs regulations in the host country with respect to the importation of *Samples* and EQAS samples, RMs and consumables from abroad and the ability to ship *Samples* outside the country as needed.

j) A description of how the principles of the ISL Code of Ethics (see section 8.0) are integrated into the laboratory's Management System as described in Article 4.1.2.3. A letter of compliance with the ISL Code of Ethics signed by the laboratory Director shall be provided.

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

#### 4.1.2.3 Compliance with the ISL Code of Ethics

The Candidate Laboratory shall implement and comply with the provision(s) of the ISL Code of Ethics (see Section 8.0).

a) A Candidate Laboratory shall not conduct any anti-doping Analytical *Testing* activities for *Signatories* or *WADA* and shall not accept *Samples* directly from individual *Athletes* or from individuals or organizations acting on their behalf.

b) The Director of the Candidate Laboratory shall provide the ISL Code of Ethics to all laboratory employees and ensure their understanding and compliance with all aspects of the ISL Code of Ethics.

#### 4.1.2.4 Laboratory Independence and Impartiality

Prior to entering the probationary period, the Candidate Laboratory shall complete a *WADA* independence and impartiality questionnaire which demonstrates that, before obtaining *WADA* accreditation, the laboratory will comply with the requirements of Laboratory independence and impartiality indicated in Article 4.1.4.2.5.

#### 4.1.2.5 Analytical *Testing* Procedures

As part of the candidate phase of *WADA* accreditation, and in preparation for the PPT EQAS, a Candidate Laboratory is expected to acquire the necessary RMs to develop their Analytical *Testing* capacity to analyze a defined list of *Prohibited Substances* and *Prohibited Methods* (provided by *WADA)* in compliance with the ISL and relevant *TD*s and *TL*s. Prior to the scheduling of the PPT and on-site assessment, the Candidate Laboratory shall provide documentation to *WADA* demonstrating that the required Analytical *Testing* capacity has been achieved.

#### 4.1.2.6 Pre-Probationary Test (PPT) and On-Site Assessment

A PPT and on-site assessment shall be conducted once *WADA* has concluded that the laboratory has successfully met the requirements of a Candidate Laboratory, as described in Articles 4.1.2.1 to 4.1.2.5, and the Candidate Laboratory has confirmed its readiness to proceed. At *WADA*'s discretion, the PPT and on-site assessment may be conducted separately or at the same time.

a) Timeline: The Candidate Laboratory should be prepared for the PPT and on-site assessment within two (2) years of *WADA* Executive Committee's approval of its Candidate Laboratory status. Any nonconformities identified during the on-site assessment or resulting from the Candidate Laboratory's performance in the PPT EQAS shall be satisfactorily resolved, as determined by the Lab EAG, by the end of the three (3) year period, unless otherwise determined by *WADA* (see Article 4.1.2.8).

b) PPT EQAS: As part of the PPT, the Candidate Laboratory shall 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 the *TD* EQAS. However, the Candidate Laboratory is not expected at this stage to have implemented all Analytical Methods or to be able to analyze all *Prohibited Substances* and *Prohibited Methods* included in the Analytical *Testing* menus of Laboratories. In this regard, *WADA* will provide guidance to the Candidate Laboratory in advance of the PPT.

c) PPT EQAS reporting: The Candidate Laboratory shall report the results for the PPT blind EQAS samples in *ADAMS* within twenty (20) days, unless otherwise notified by *WADA*.

   i. Upon request, the Candidate Laboratory shall provide *WADA* with a LDOC for selected EQAS sample(s) for which there is an *AAF*. Additional data may be required upon *WADA*'*s* request. This documentation shall be submitted within ten (10) days of *WADA*'s request or as otherwise indicated by *WADA*.

   ii. For selected EQAS samples with Negative Findings, *WADA* may request all or a portion of the ITP data.

d) PPT EQAS evaluation: 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 for nonconformities, if any, shall be conducted and reported by the Candidate Laboratory to *WADA* within thirty (30) days, or as otherwise indicated by *WADA*.

e) PPT on-site assessment: *WADA* shall conduct the 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, which are relevant to the *WADA* accreditation and to clarify any issues regarding the accreditation process.

   If relevant, a representative of the laboratory's ISO/IEC 17025 Accreditation Body may be invited as an observer to the *WADA* on-site assessment.

f) PPT on-site assessment evaluation: *WADA* shall provide a PPT Assessment Report regarding the outcomes of the on-site assessment, including any identified nonconformity(-ies), to allow the Candidate Laboratory to implement the necessary improvements.

   i. Assessment findings for major and minor nonconformities, if requested by *WADA*, shall be addressed by the Candidate Laboratory, and reported to *WADA* within thirty (30) days, or as otherwise indicated by *WADA*.

   ii. The nonconformities identified in the *WADA* PPT Assessment Report shall be satisfactorily addressed, as determined by the Lab EAG, and the recommendations for improvement should be implemented before the Candidate Laboratory can be accepted as a *WADA* Probationary Laboratory.

   iii. The Candidate Laboratory's performance in the PPT EQAS and on-site assessment will be considered in the overall review of the Candidate Laboratory' s application and may affect the timeliness of the Candidate Laboratory's entry into the probationary phase of accreditation.

#### 4.1.2.7 Payment of Probationary Phase 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 probationary phase accreditation activities, including the review of documentation and any necessary follow ups, as well as the preparation, characterization, and shipment of the EQAS samples necessary for the probationary period and the Final Accreditation Test (FAT) - see Articles 4.1.3.4. and 4.1.3.10. This fee shall be determined by *WADA*.

#### 4.1.2.8 Duration of Candidate Phase of *WADA* Accreditation

a) 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.

b) A Candidate Laboratory that fails to meet the requirements to enter the probationary phase of accreditation after three (3) years may lead to a Lab EAG recommendation to the *WADA* Executive Committee to have its Candidate Laboratory status revoked.

c) Upon request, a revoked Candidate Laboratory that wishes to continue seeking *WADA* accreditation will be required to apply again for Candidate Laboratory status as described in Article 4.1.1.

### 4.1.3 Probationary Laboratory for *WADA* Accreditation

#### 4.1.3.1 Entering the Probationary Phase of *WADA* Accreditation

Upon satisfactory completion of all Candidate Laboratory requirements (as per Article 4.1.2), a Candidate Laboratory may enter the probationary phase of *WADA* accreditation as a Probationary Laboratory, as determined by *WADA* (upon advice by the Lab EAG).

#### 4.1.3.2 Compliance with the ISL Code of Ethics

The Probationary Laboratory shall implement and comply with the provision(s) of the ISL Code of Ethics (see Section 8.0).

a) A Probationary Laboratory shall not conduct any anti-doping Analytical *Testing* activities for *Signatories* or *WADA* and shall not accept *Samples* directly from individual *Athletes* or from individuals or organizations acting on their behalf.

b) The Director of the Probationary Laboratory shall provide the ISL Code of Ethics to all laboratory employees and ensure their understanding and compliance with all aspects of the ISL Code of Ethics.

#### 4.1.3.3 Provision of Renewed Letters of Support

The Probationary Laboratory shall submit renewed letters of support upon *WADA* request:

a) Official letter(s) of support from the laboratory's host organization(s) (*e.g.*, universities, hospitals, private organizations and/or public institutions). The letter(s) of support shall 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 and research and development (R&D) activities.

b) Official letter(s) of support from *Signatories,* e.g.*, NADO*s or *RADO*s responsible for National Anti-Doping Program(s), International Federation(s) responsible for International Anti-Doping Program(s), *DTP*s in charge of *Doping Control* activities on behalf of *ADO*s. The letter(s) of support shall indicate a commitment to provide the Laboratory with a minimum total of 3,000 *Samples* (including urine, blood, *ABP* blood and DBS *Samples*) per year, of which at least 2,500 shall be urine *Samples,* by the end of the first full calendar year after obtaining *WADA* accreditation.

*[Comment to Article 4.1.3.3 b): To determine the minimum number of Samples, each urine Sample, blood Sample, ABP blood Sample and DBS Sample analyzed by the Laboratory shall count as an individual Sample.]*

c) A declaration by the supporting *Signatory*(-ies) that their relationship with the Probationary Laboratory is compliant with Article 4.1.4.2.5.

#### 4.1.3.4 Participating in the *WADA* EQAS Program

As part of the probationary phase, the Probationary Laboratory is expected to gradually develop full capacity for the analysis of *Prohibited Substances* and *Prohibited* Methods as required from *WADA*-accredited laboratories.

a) During the probationary period, the Probationary Laboratory shall successfully analyze at least fifteen (15) blind EQAS samples, distributed over multiple EQAS rounds within a period of approximately twelve (12) months. During this period, *WADA* shall provide feedback to assist the Probationary Laboratory to improve the quality of its Analytical *Testing* procedures.

b) The Probationary Laboratory shall successfully report the results for the blind EQAS samples to *WADA*, in accordance with the *TD* EQAS, 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 the *TD* EQAS and the *TD* PERF, respectively.

#### 4.1.3.5 Planning and Implementing Research and Development (R&D) and Sharing of Knowledge Activities

Prior to obtaining *WADA* accreditation, the Probationary Laboratory shall develop a plan for its R&D and Sharing of Knowledge activities in the field of anti-doping science, for the initial two (2)-year period following *WADA* accreditation, including the following requirements:

a) At least two (2) R&D activities (e.g., new research projects, Analytical Method development) shall be initiated as soon as possible and implemented within the probationary period. The research activities may be carried out either by the Probationary Laboratory alone or in cooperation with Laboratories or in association with research organizations.

b) During the probationary period, the Probationary Laboratory shall demonstrate its willingness and ability to collaborate and share knowledge with Laboratories.

c) As part of its laboratory monitoring activities, *WADA* may request documented evidence of the R&D and Sharing of Knowledge activities in the field of anti-doping science undertaken by the Probationary Laboratory.

#### 4.1.3.6 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 Section 5.0).

a) 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).

b) The Accreditation Body should send a summary of the ISO/IEC 17025 Assessment Report and any corrective 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 and is required before *WADA* grants accreditation.

#### 4.1.3.7 Laboratory Independence and Impartiality

Before *WADA* grants accreditation, the Probationary Laboratory shall provide documentation to *WADA* demonstrating compliance with the requirements of Laboratory independence and impartiality established in Article 4.1.4.2.5.

#### 4.1.3.8 Professional Liability Insurance Coverage

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

#### 4.1.3.9 Analytical *Testing* Procedures

Before *WADA* grants accreditation, the Probationary Laboratory shall provide documentation to *WADA* demonstrating that all mandatory Test Methods have been validated, as determined by *WADA*, and included in the Laboratory's Scope of ISO/IEC 17025 accreditation.

*WADA* will inform the Probationary Laboratory on the Test Methods that shall be validated to obtain accreditation.

#### 4.1.3.10 *WADA* Accreditation Assessment - Final Accreditation Test (FAT)

A FAT and on-site assessment shall be conducted once *WADA* has determined that the Probationary Laboratory has successfully completed all the requirements of the probationary period, and the Probationary Laboratory has confirmed its readiness to proceed. At *WADA*'s discretion, the FAT and on-site assessment may be conducted separately or at the same time.

The FAT shall assess both the scientific competence and the capability of the Probationary Laboratory to manage multiple *Sample*s.

a) Timeline: The Probationary Laboratory should prepare to successfully participate in the FAT and on-site assessment within two (2) years of obtaining their probationary status. The Probationary Laboratory shall satisfactorily address, as determined by *WADA*, all identified nonconformities and meet all conditions under Article 4.1.3 by the end of the three (3) year period, unless otherwise determined by *WADA* (see Article 4.1.3.11).

   At this stage, the Probationary Laboratory is expected to have developed full capacity for the analysis of *Prohibited Substances* and *Prohibited Method*s as mandatorily required from *WADA*-accredited laboratories. Therefore, compliance with the defined requirements in the Application of ISO/IEC 17025 to the analysis of *Samples*, the ISL and other *WADA* Laboratory standards (*TD*s, *TL*s, LGs), and the practice and documentation of the laboratory, will be assessed.

b) FAT EQAS: As part of the FAT, the Probationary Laboratory shall analyze a minimum of fifteen (15) blind EQAS samples. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in the *TD* EQAS and the *TD* PERF, respectively.

c) FAT EQAS reporting: The Probationary Laboratory shall successfully report the results for the blind EQAS samples in the FAT to *WADA* within seven (7) days of opening the samples, unless otherwise determined by *WADA*. In addition:

   i. Upon request, the Probationary Laboratory shall provide *WADA* with LDOCs for selected EQAS sample(s) for which there is an *AAF*. Additional data may be required upon *WADA*'s request. This documentation shall be submitted within ten (10) days of *WADA*'s request or as otherwise indicated by *WADA*.

   ii. For EQAS samples with Negative Findings, *WADA* may request all or a portion of the ITP data.

d) FAT EQAS evaluation: After receiving the FAT EQAS results, *WADA* shall inform the Probationary Laboratory of the evaluation of its performance.

i. Corrective actions for nonconformities, if any, shall be conducted and reported by the Probationary Laboratory to *WADA* within thirty (30) days, or as otherwise indicated by *WADA*.

ii. The nonconformities identified in the FAT EQAS shall be satisfactorily addressed by the Probationary Laboratory and the recommendations for improvement should be implemented before accreditation can be granted.

e) FAT on-site assessment: *WADA* shall conduct the on-site assessment of the Probationary Laboratory at the Probationary Laboratory's expense.

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

f) FAT on-site assessment evaluation: *WADA* shall provide an FAT Assessment Report with the outcomes of the on-site assessment, including any identified nonconformity(-ies) for the Probationary Laboratory to implement the necessary improvements.

i. Identified nonconformities shall be addressed by the Probationary Laboratory and corrective measures reported to *WADA* within thirty (30) days, or as otherwise indicated by *WADA*.

ii. The nonconformities identified in the FAT Assessment Report shall be satisfactorily addressed by the Probationary Laboratory and the recommendations for improvement should be implemented before accreditation can be granted.

g) The Probationary Laboratory's performance in the FAT and on-site assessment will be considered in the overall review of the Probationary Laboratory's application and may affect the Probationary Laboratory's timeliness for obtaining *WADA* accreditation.

i. If following the FAT EQAS and on-site assessment, *WADA* determines that nonconformities have not been satisfactorily addressed and that, consequently, the Probationary Laboratory should not be accredited, the laboratory will have a maximum of one (1) year to correct and improve any pending nonconformity(-ies).

ii. The provision of documentation, the analysis of additional EQAS samples and/or an additional assessment (on-site, remotely or as a documentary audit, as determined by *WADA*), may be required and conducted at the Probationary Laboratory's expense.

iii. A Probationary Laboratory that fails to provide satisfactory improvements, as determined by *WADA*, after one (1) year (from the date that the Assessment Report is issued) may be required to

reapply for Candidate Laboratory status as described in Article 4.1 (see also Article 4.1.3.11).

#### 4.1.3.11 Duration of Probationary Phase of *WADA* Accreditation

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

b) A Probationary Laboratory that fails to meet the requirements to become *WADA*-accredited after three (3) years may lead to a Lab EAG recommendation to the *WADA* Executive Committee to revoke its probationary status.

c) Upon request, a revoked probationary laboratory that wishes to continue its *WADA* accreditation process will be required to reapply for Candidate Laboratory status as described in Article 4.1.

### 4.1.4 *WADA*-Accredited Laboratory

#### 4.1.4.1 Obtaining *WADA* accreditation

##### 4.1.4.1.1 Granting of *WADA* Accreditation

Once the Lab EAG has evaluated the Probationary Laboratory's progress and determined that all accreditation requirements (outlined in Articles 4.1.3.2 to 4.1.3.10) have been satisfactorily met, the Lab EAG will submit a recommendation that the laboratory be granted *WADA* accreditation to the *WADA* Executive Committee for approval.

The new *WADA*-accredited laboratory shall obtain a second opinion from an(other) Laboratory(-ies) before reporting an *AAF* or *ATF*, for a period of one (1) year after obtaining *WADA* accreditation. *WADA* may extend the second opinion requirement beyond one (1) year.

##### 4.1.4.1.2 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 Laboratory's *WADA* accreditation. The 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, and relevant contact information, shall be published on *WADA*'*s* website.

#### 4.1.4.2 Maintaining *WADA* Accreditation

A Laboratory shall comply with the following requirements to maintain *WADA* accreditation:

##### 4.1.4.2.1 Payment of Annual Re-Accreditation Fee

*WADA* will invoice the Laboratory for a non-refundable annual re-accreditation fee to partially cover the costs related to the re-accreditation process, including the Laboratory's participation in the *WADA* EQAS as well as other Laboratory-related monitoring activities. This fee shall be determined by *WADA*.

##### 4.1.4.2.2 Document Compliance with the ISL Code of Ethics

The Laboratory shall maintain and document compliance with the provision(s) of the ISL Code of Ethics (see Section 8.0).

a) All staff employed at the Laboratory, permanent or temporary, shall also read, agree to and sign the ISL Code of Ethics.

b) The Laboratory shall establish a system requiring Laboratory staff to report any alleged breaches of the ISL Code of Ethics to the Laboratory Director, which the Laboratory Director shall report to *WADA*. However, if Laboratory staff suspect that the Laboratory Director may have breached the ISL Code of Ethics, the Laboratory staff shall report the alleged breaches of the ISL Code of Ethics directly to *WADA*. The Laboratory Director and/or the Laboratory's host organization and/or *WADA*, as applicable, shall immediately and thoroughly investigate any alleged breach of the ISL Code of Ethics.

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

d) On an annual basis, and upon *WADA's* request, the Laboratory shall provide a letter of compliance with the provisions of the ISL Code of Ethics, signed by the Laboratory Director.

e) Upon *WADA's* request, the Laboratory shall provide additional documentation of compliance with the provisions of the ISL Code of Ethics.

#### 4.1.4.2.3 Maintain Professional Liability Insurance Coverage

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

#### 4.1.4.2.4 Maintain ISO/IEC 17025 Accreditation

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

a) 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.

b) Laboratories shall include Analytical *Testing* Procedures within their Scope of ISO/IEC 17025 Accreditation prior to application to the analysis of *Samples*.

   i. However, under exceptional circumstances, a Laboratory may apply a method, which has been validated in accordance with applicable *TD*s*, TL*s or LGs, to the analysis of *Samples* before inclusion into the Laboratory's Scope of ISO/IEC 17025 Accreditation.

   ii. In such cases, the Laboratory would not automatically benefit from the presumption that the method is Fit-for-Purpose, as would otherwise be the case if the Analytical *Testing* Procedure is included within the Laboratory's Scope of ISO/IEC 17025 Accreditation.

   iii. Consequently, any *AAF* reported by applying a Test Method, which is not within the Laboratory's Scope of ISO/IEC 17025 Accreditation, may require the Laboratory to provide method validation documentation or EQAS performance data in support of that *AAF*.

c) Flexible Scope of ISO/IEC 17025 Accreditation [3]

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

*[Comment to Article 4.1.4.2.4. c): The flexible system of ISO/IEC 17025 Laboratory accreditation shall be based on the assessment by the Accreditation Body that the Laboratory has the demonstrated competence to implement Laboratory processes and procedures 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 promptly adapt their Analytical Testing Procedures to detect new Prohibited Substances or Prohibited Methods, as well apply new technical and scientific developments in Analytical Testing for Doping Control.]*

d) The Laboratories are not eligible to apply a Flexible Scope of ISO/IEC 17025 Accreditation to the analysis of *Samples* in the following scenarios:

i. New Analytical *Testing* Procedures

Any Analytical *Testing* Procedure which is new to the field of anti-doping analysis shall be approved by *WADA* as Fit-for-Purpose prior to implementation by a 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 Method is Fit-for-Purpose prior to providing formal approval.

Before a new Analytical *Testing* Procedure can be *applied* to the analysis of *Samples,* a Laboratory shall obtain an extension of their Scope of ISO/IEC 17025 Accreditation by their Accreditation Body and may be required to successfully participate in an inter-laboratory collaborative study or a *WADA* EQAS, if available.

ii. *WADA*-specific Analytical *Testing* Procedures

*WADA* will require the Laboratory to seek an *extension* of their Scope of ISO/IEC 17025 Accreditation for *WADA*-

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

specific Analytical *Testing* Procedures before application to the analysis of *Samples*, even if the analytical technique involved is already incorporated in the Laboratory's Scope of ISO/IEC 17025 Accreditation.

*WADA* will communicate to the Laboratories and to the Accreditation Bodies which Analytical *Testing* Procedures are included in this category.

In such cases, the Analytical *Testing* Procedure shall be validated by the Laboratory. The Laboratory may also be required to successfully participate in an inter-laboratory collaborative study or *WADA*-organized EQAS round to obtain an extension to the Scope of ISO/IEC 17025 Accreditation by a relevant Accreditation Body before introducing the Analytical *Testing* Procedure to the analysis of *Samples*. However, once a *WADA*-specific Analytical *Testing* Procedure is included within the Scope of ISO/IEC 17025 Accreditation, limited changes to this Analytical *Testing* Procedure may be allowed within the boundaries of a Flexible Scope of ISO/IEC 17025 Accreditation.

Nonetheless, the Laboratories shall not flexibly introduce new Analytes within a *WADA*-specific Analytical *Testing* Procedure if specific method performance or reporting criteria (e.g.*, DLs*) are necessary and those criteria are not yet defined in an applicable *TD* or *TL* (e.g.*,* new target compound(s) for GC/C/IRMS analysis). In such cases, the Laboratory would have to request an extension to the Scope of ISO/IEC 17025 Accreditation and provide to the Accreditation Body all necessary data and information supporting their method performance or reporting criteria.

*[Comment to Article 4.1.4.2.4 d): Laboratories shall not apply a WADA-specific Analytical Testing Procedure to the analysis of Samples until the Test Method, and the Analyte(s) included in the Test Method, are included in the Laboratory's Scope of ISO/IEC 17025 Accreditation.]*

#### 4.1.4.2.5 Laboratory Independence and Impartiality

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

a) To be administratively independent, the Laboratory shall not be administered by, connected or subject to an *Anti-Doping Organization,* sport organization or government Ministry of Sport or other government body or subsidiary responsible

for or related to sport performance, including their Board Members, staff, Commission Members, or officials. This is necessary to avoid any potential conflicts of interest and ensure full Laboratory independence in their Analytical *Testing* and reporting procedures, and to provide confidence in the Laboratory's impartiality, judgment, and operational integrity, in compliance with ISO/IEC 17025.

b) To be operationally independent, the Laboratory shall manage its own management system and operational affairs without obstruction, interference, or manipulation from any *Person*. The Laboratory shall, without limitation, control: the allocation of its budget, the procurement of equipment and other resources, Laboratory personnel decisions, the research conducted by the Laboratory and all *Sample* Analytical *Testing* and reporting of results.

c) The Laboratory shall have a dedicated budget allowing the implementation of an efficient approval process for the timely procurement of necessary RMs, 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, private organization, public institution), *ADO*s, sport organizations, government, or other sponsors, while following applicable accounting regulations in connection with the receipt and management of those funds.

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

#### 4.1.4.2.6 Participate in the *WADA* EQAS Program

Laboratories shall participate in the *WADA* EQAS on a continuous basis and meet the performance requirements of the EQAS as described in the *TD* EQAS.

#### 4.1.4.2.7 Providing Renewed Letter(s) of Support

*WADA* reserves the right to request Laboratories to provide renewed letter(s) of support, as described in Article 4.1.1.3, from *Signatories* based on the assessment of the Laboratory annual *Testing* figures, or as otherwise determined by *WADA.*

#### 4.1.4.2.8 Maintain Minimum Number of *Samples*

To maintain proficiency in Analytical *Testing*, Laboratories are required to analyze a minimum of 3,000 *Samples* (including urine, blood, *ABP* blood and DBS *Samples*) per year, of which at least 2,500 shall be urine *Samples*, provided annually by *Signatories*.

*[Comment to Article 4.1.4.2.8: To determine the minimum number of Samples, each urine Sample, blood Sample, ABP blood Sample and DBS Sample analyzed by the Laboratory shall count as an individual Sample.]*

*WADA* will monitor the number of *Samples* tested by the Laboratory. If the total number of *Samples* analyzed for *Signatories* falls below 3,000 per year (or below 2,500 urine *Samples* per year), the Laboratory's *WADA* accreditation may be suspended in accordance with Article 7.1.1.1.

However, it is recognized that specific circumstances may affect a Laboratory's ability to analyze the minimum number of *Samples* annually, such as when a *Signatory* is declared non-compliant with the *Code* by *WADA*, or when the Laboratory is not operational, for reasons accepted by *WADA*. In such cases, the Laboratory's *WADA* accreditation status may not be affected but *WADA* will require that the Laboratory implement measures to maintain its proficiency in Analytical *Testing*, for example by strengthening its internal Quality Assurance Scheme (iQAS) and internal audits program. *WADA* may also provide additional EQAS samples and/or conduct a documentary audit and/or an on-site or remote (on-line) assessment, at its discretion, to assess the status of the Laboratory's operations.

#### 4.1.4.2.9 Implement Research and Development (R&D) and Sharing of Knowledge Activities

The Laboratory shall implement R&D activities in the field of anti-doping science. The Laboratory shall also demonstrate its willingness and ability to share its knowledge with other Laboratories in the field. The maintenance by the Laboratory of an adequate R&D and Sharing of Knowledge program is a mandatory condition for maintaining *WADA* accreditation.

a) The Laboratory shall develop an R&D program to support and expand the scientific foundation of *Doping Control*.

*[Comment to Article 4.1.4.2.9 a): This research may include the development of new Analytical Methods or technologies for detection of Use of Prohibited Substances or Prohibited Methods, the pharmacological characterization of a new doping agent, the chemical synthesis of emerging substances/ Metabolites, the preparation of biological reference samples or the discovery of new biomarkers of doping, and other topics relevant to the field of Doping Control.]*

b) When the Laboratory becomes aware of information on new doping substance(s), method(s), or practice(s), either through the production of new knowledge by the Laboratory (for instance based on untargeted analytical approaches) or by other means, such information shall be reported to *WADA* within sixty (60) days. To the extent possible, the Laboratories shall share information regarding the detection of potentially new or rarely detected doping agents with *WADA* as soon as possible. Immediately upon learning of the *Use* of a new substance or method as a doping agent, *WADA* shall notify all Laboratories.

c) The Laboratory shall participate in developing standards of best practice and enhancing uniformity of Analytical *Testing* in the *WADA*-accredited laboratory system.

*[Comment to Article 4.1.4.2.9 c): Sharing of knowledge can be achieved in a variety of ways, including but not limited to, communicating directly with WADA, actively participating in scientific meetings, publishing results of research, sharing of specific details of Analytical Methods, working with WADA to produce and/or distribute new RM(s) or RC(s).]*

d) The Laboratory shall document in its Management System the organization and planning of their R&D and Sharing of Knowledge activities, including but not limited to, the following:

i. An R&D unit/department, clearly identified on the Laboratory organigram.

*[Comment to Article 4.1.4.2.9 d): The R&D unit/department shall define its objectives, the deliverables envisaged, the timetable for achieving them, and the knowledge dissemination scheme (e.g., number of papers to be published in international peer-reviewed scientific journals, number of collaborative projects, number of poster communications, participation in anti-doping science events, staff participation in training sessions and provision of training opportunities to other Laboratories, probationary laboratories or Candidate Laboratories). The Laboratory shall also define the frequency with which the R&D objectives should be reviewed and updated].*

ii. A qualified *Person*(s) responsible for R&D activities. The qualifications should include:

- A Master's or PhD degree in one of the natural or life sciences;
- Ability to plan and execute research projects within budget and on schedule;
- Sound technical knowledge in *Doping Control*, including the *Code* and ISL requirements to conduct anti-doping research (refer to *Code* Articles 6.3 and 19, and ISL Article 5.3.8.2) as well as national and

international regulations for conducting research in humans;

- Communication skills to enable the research results to be communicated effectively (verbally and in writing) and to be promoted through the writing of scientific papers.

iii. A defined annual R&D budget. Describe the R&D funding strategy, including sources of funding (e.g., internal, institutional, external providers of research grants) to achieve adequate R&D outcomes.

iv. Consideration of ethical aspects of R&D (see ISL Code of Ethics) and, where appropriate, a plan for the development and protection (through patents, trademarks, and other legal mechanisms) of any intellectual property.

v. A Management System document pertaining to the secondary use of *Samples* or Aliquots for research or *Quality Assurance* purposes, including the requirement to obtain *Athlete* consent for use of *Samples* for research purposes and a procedure for de-identification of *Samples* and Aliquots (see also Article 5.3.8.2).

e) The Laboratory shall make every effort, in consideration of its human, financial and technical resources, to attain adequate R&D outcomes and contribute to the advancement of anti-doping science. The Laboratory shall meet the following minimum targets as part of their R&D and Sharing of Knowledge programs:

i. Publish at least one (1) publication every two (2) years in an indexed and peer-reviewed international scientific journal with an associated impact factor.

*[Comment to Article 4.1.4.2.9 e): The publication(s) may also include co-authored papers resulting from collaborative studies. In such cases, WADA may request the Laboratory to provide a Contributor Roles Taxonomy (CrediT) statement.]*

ii. Make at least one (1) annual contribution to a national or international anti-doping symposium or conference.

iii. In addition, the Laboratory is encouraged to participate in collaborative research projects with other Laboratories, and exchange experience, protocols, arrange for visits of specialists, and provide training to other Laboratories and probationary laboratories in specific areas of Analytical *Testing*.

iv. On a biennial basis, and upon provision of a template report by *WADA*, the Laboratory shall produce a R&D and Sharing of Knowledge Activity Report, which will serve as the basis for assessing the Laboratory's contribution to the development of anti-doping science.

- Following the evaluation of the Laboratory's R&D and Sharing of Knowledge Activity Report by the Lab EAG, corrective actions may be requested from the Laboratory to address and improve identified deficiencies;
- Failure to satisfactorily address the identified deficiencies in a reasonable timeframe, as determined by the Lab EAG, may result in the assignment of penalty points (see *TD* PERF) and/or in a Lab EAG's recommendation to the Chair of the *WADA* Executive Committee to suspend the Laboratory's *WADA* accreditation.

#### 4.1.4.2.10 Publication of Laboratory Analytical *Testing* Procedures, Services and Fees

The Laboratory shall report and maintain in *ADAMS* an up-to-date list of Analytical *Testing* Procedures and services, including standard prices, to assist *ADO*s in developing TDPs.

Upon request by an *ADO*, the Laboratory should cooperate by providing other relevant information (e.g., Laboratory analytical capabilities) to assist the *ADO* with their *Testing* plans.

#### 4.1.4.2.11 Participating in *WADA* / Accreditation Body Assessments

a) Accreditation Body assessment during the Accreditation Cycle

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

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

iii. 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.

b) *WADA* Laboratory Assessment

*WADA* reserves the right to conduct document audits and/or on-site and/or remote (on-line) assessments of the Laboratory at any time, at *WADA*'s expense. The notice of a *WADA* assessment will be made in writing to the Laboratory Director. In exceptional circumstances, and at *WADA*'s discretion, the assessment may be unannounced (for more information on *WADA* Laboratory assessments, see Article 6.1.2).

#### 4.1.4.2.12 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 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, and their contact information, is maintained on *WADA*'s website.

## 4.2 *WADA ABP* Laboratory Approval

The network of *WADA*-accredited laboratories may be geographically limited to serve the practical development of the Hematological Module of the *ABP*. Therefore, non-*WADA*-accredited laboratories, which have the capability to analyze the blood *Markers* of the *ABP*, may apply for *WADA* approval for the purposes of analyzing blood *Samples* in support of the Hematological Module of the *ABP* if located in a region that cannot be served by a Laboratory. This Article describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining *WADA* approval for the *ABP*.

### 4.2.1 Applicant *ABP* Laboratory

In principle, a laboratory that satisfies the criteria listed below may apply to become a Candidate *ABP* Laboratory. However, the *WADA* Executive Committee, at its sole discretion, may accept or deny a laboratory's 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).

[*Comment to Article 4.2.1: Once a laboratory has been approved as a Candidate Laboratory for WADA accreditation, as per Article 4.1.2, that status is also applicable to the analysis of ABP blood Samples.]*

#### 4.2.1.1 Expression of Interest

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

#### 4.2.1.2 Submit Initial Application Form

The Applicant *ABP* Laboratory shall submit a completed initial application form, provided by *WADA*, with supporting documentation for review by the Lab EAG.

An Applicant *ABP* Laboratory may only submit an application if its host country satisfies the following conditions:

a) The existence of a robust National Anti-Doping Program conducted by a *NADO* and/or a *RADO* which is compliant with the *Code* and the *International Standards* of the World Anti-Doping Program.

*[Comment Article 4.2.1.2 a): The host country's National Anti-Doping Program will be evaluated regarding their TDP, Sample collection and Results Management activities.]*

b) The National Anti-Doping Program in the host country of the Applicant *ABP* Laboratory shall have demonstrated, in the most recent full year, that its *Sample* collection activities included the analysis of at least 200 blood *ABP Samples,* collected in compliance with the IST (as determined by *WADA*) and analyzed in a Laboratory(-ies) or *ABP* Laboratory(-ies).

c) The ratification of the UNESCO Convention against Doping in Sport, and

d) The payment of the annual financial contributions to *WADA*.

These conditions shall be documented as part of the application.

#### 4.2.1.3 Provision of Letter(s) of Support

Upon receipt of an application and verification of the conditions mentioned above, *WADA* shall request that the Applicant *ABP* Laboratory submit letter(s) of support from *Signatories,* such as *NADO*s or *RADO*s responsible for National Anti-Doping Program(s), or International Federation(s) responsible for International Anti-Doping Program(s), or *DTP*s in charge of *Doping Control* activities on behalf of *ADO*s, guaranteeing a minimum total number of 300 *ABP Samples* annually. The letter(s) of support shall indicate:

a) The estimated number of *ABP* blood *Samples* that will be provided to the Applicant *ABP* Laboratory annually; and

b) The reason(s) why an existing Laboratory or *ABP* Laboratory is not a viable option for the *Signatory's ABP* program.

c) A declaration by the supporting *Signatory* that their relationship to the Applicant *ABP* Laboratory is compliant with Article 4.1.4.2.5.

#### 4.2.1.4 Provision of Business Plan

The Applicant *ABP* Laboratory shall submit a business plan, upon request by *WADA*, 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. The business plan shall be provided by the Applicant *ABP* Laboratory within eight (8) weeks of *WADA*'s request.

### 4.2.2 Candidate *ABP* Laboratory

The application materials described in Articles 4.2.1.2 to 4.2.1.4 shall be evaluated by *WADA*. If *WADA*, upon advice by the Lab EAG, determines that the applicant *ABP* Laboratory has satisfactorily met the criteria of Article 4.2.1, a recommendation will be forwarded to the *WADA* Executive Committee to determine whether the Applicant *ABP* Laboratory will be granted *WADA* Candidate *ABP* Laboratory status and thereby continue within the *WADA* approval process. Additional supporting documentation may be requested by, and at the discretion of, the *WADA* Executive Committee

#### 4.2.2.1 Candidate *ABP* Laboratory Administrative and Technical Capabilities

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

a) List of laboratory staff that will be responsible for the *ABP* analyses and their qualifications.

b) Laboratory facilities and physical security: see Article 5.2.3.1.

c) IT infrastructure and security: see Article 5.2.3.5.

d) List of actual and proposed instrumental resources and equipment for the *ABP*.

e) Status of the *ABP* method development and validation. Method validation report (if completed).

f) Status of ISO/IEC 17025 or ISO 15189 accreditation.

g) Status of Laboratory's independence and impartiality as described in Article 4.1.4.2.5

h) Description of customs regulations in the host country with respect to the importation of blood *Samples* and consumables and the ability to ship blood *Samples* outside the country as needed.

i) A description of how the principles of the ISL Code of Ethics are integrated into the laboratory's Management System as described in Article 4.2.2.2.

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

*[Comment to Article 4.2.2.1: The Candidate ABP Laboratory is encouraged to establish agreement(s) with a Laboratory(-ies) for mentoring and training to ensure successful preparation towards obtaining the WADA ABP approval.]*

#### 4.2.2.2 Compliance with the ISL Code of Ethics

The Candidate *ABP* Laboratory shall implement and comply with the provision(s) of the ISL Code of Ethics (see Section 8.0).

a) The Candidate *ABP* Laboratory shall not conduct any anti-doping Analytical *Testing* activities for *Signatories* or *WADA* and shall not accept *Samples* directly from individual *Athletes* or from individuals or organizations acting on their behalf.

b) The Director of the Candidate *ABP* Laboratory shall provide the ISL Code of Ethics to all laboratory employees operating in the *ABP* and ensure their understanding and compliance with all aspects of the ISL Code of Ethics.

c) A letter of compliance with the ISL Code of Ethics shall be signed by the laboratory Director and provided to *WADA*.

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

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

#### 4.2.2.4 Laboratory Independence and Impartiality

Before *WADA* grants *ABP* approval and to avoid potential conflicts of interest, the laboratory shall complete a *WADA* independence and impartiality questionnaire which demonstrates that, before obtaining *WADA ABP* approval, the laboratory will comply with the requirements of Laboratory independence and impartiality indicated in Article 4.1.4.2.5.

#### 4.2.2.5 Obtaining ISO/IEC 17025 or ISO 15189 Accreditation

The Candidate *ABP* Laboratory shall obtain ISO/IEC 17025 or ISO 15189 accreditation from an Accreditation Body.

a) 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).

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

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

d) 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 Candidate *ABP* 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 *ABP* approval can be granted.

#### 4.2.2.6 Professional Liability Insurance Coverage

Before *WADA* grants *ABP* approval, the Candidate *ABP* Laboratory shall provide documentation to *WADA* that professional liability risk insurance coverage has been obtained to cover liability of no less than one (1) million USD annually.

#### 4.2.2.7 *WADA* On-Site Assessment for the *ABP* Approval

*WADA* shall conduct an on-site assessment of the Candidate *ABP* Laboratory once *WADA* has determined that the laboratory has successfully completed all the requirements outlined in Articles 4.2.2.1 to 4.2.2.6.

*[Comment to Article 4.2.2.7: The purpose of this assessment is to obtain information about different aspects of the Candidate Laboratory's competence and verify compliance with the relevant ISL and TD requirements (in particular, the TD BAR)).*

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

a) The on-site assessment shall be conducted at the Candidate *ABP* Laboratory's expense.

b) The Candidate *ABP* Laboratory shall have participated in a minimum of one (1) *WADA* EQAS round before the on-site assessment is conducted.

c) *WADA* shall provide an Assessment Report regarding the outcomes of the on-site assessment, including any identified nonconformity(-ies), to allow the Candidate *ABP* Laboratory to implement the necessary improvements. Nonconformities shall be satisfactorily addressed and reported by the Candidate *ABP* Laboratory to *WADA* within thirty (30) days, or as otherwise indicated by *WADA*.

d) The nonconformities identified in the *WADA* Assessment Report shall be satisfactorily addressed and the recommendations for improvement should be implemented before the end of the candidate *ABP* approval phase as per Article 4.2.2.8.

The laboratory's performance in the *WADA* EQAS and on-site assessment will be considered in the overall review of the laboratory's status and may affect the timeliness of the *WADA* approval.

#### 4.2.2.8 Duration of Candidate *ABP* Approval Phase

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

### 4.2.3 *ABP* Laboratory

#### 4.2.3.1 Granting of *WADA ABP* Approval

Once the Lab EAG has evaluated the Candidate *ABP* Laboratory's progress and determined that all approval requirements (outlined in Articles 4.2.2) have been satisfactorily met, the Lab EAG will submit a recommendation to the *WADA* Executive Committee to grant the laboratory the status of an *ABP* Laboratory.

#### 4.2.3.2 Issuing and Publishing of *WADA ABP* Approval Certificate

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*) shall be issued in recognition of the Laboratory's *WADA ABP*-approval.

The *WADA ABP* Approval Certificate shall specify the name of the *ABP* Laboratory and the period of validity. *WADA ABP* Approval Certificates may be issued after the effective date of the *WADA* approval, with retroactive effect.

A list of *ABP* Laboratories, and their contact information, shall be maintained on *WADA*'s website for stakeholder reference.

#### 4.2.3.3 Maintaining *ABP* Laboratory Status

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

a) Documented compliance with the ISL Code of Ethics (Annex A).

b) Maintenance of Professional Liability Insurance Coverage to cover liability of no less than one (1) million USD annually.

c) Maintenance of a valid ISO accreditation (ISO/IEC 17025 or ISO 15189).

d) Maintenance of laboratory independence and impartiality (see Article 4.1.4.2.5).

e) 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.*

f) Payment of fees related to the *WADA* EQAS or similar *WADA*-approved *Quality Assurance* program for the analysis of *ABP* blood *Markers*.

g) Availability of the relevant analytical instrumentation and consumables (e.g.*,* quality control samples, reagents), which is compliant with the requirements of the Hematological Module of the *ABP*, as determined by *WADA*.

h) Implementation of the Analytical *Testing* Procedure(s) for the measurement of individual *Athlete* blood *Markers*, which are compliant with the *TD* BAR.

i) Compliance with relevant *WADA* normative documents, including the relevant articles of ISL Section 5.0 and *TD*s and *TL*s applicable to the analysis of *ABP* blood *Samples* (e.g.*, TD* LDOC, *TD* LCOC).

j) Provision of Letter(s) of support from *Signatories*, if requested by *WADA*, as described in Article 4.2.1.3*.*

k) Analysis of a minimum of 300 *ABP* blood *Samples* provided annually by *Signatories*.

l) Maintaining up-to-date prices in *ADAMS* for blood *ABP* analytical services to assist *ADO*s in developing TDPs. Upon request by an *ADO*, *ABP* Laboratories should cooperate with the *ADO* by providing other relevant information regarding *Testing* plans (e.g.*, ABP* Laboratory analytical capabilities).

m) Participation in *WADA* / Accreditation Body assessments (see Article 4.1.4.2.11).

n) Cooperation in support of the administrative and legal processes instigated when anti-doping rule violations are issued and managed by *ADO*s.

#### 4.2.3.4 Issuing and Publishing of *WADA ABP* Approval Certificate

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

b) The *WADA ABP* Approval Certificate shall specify the name of the *ABP* Laboratory and the period of validity. *WADA ABP* Approval Certificates may be issued after the effective date of the *WADA* approval, with retroactive effect.

c) A list of *ABP* Laboratories, and their contact information, shall be maintained on *WADA*'s website for stakeholder reference.

### 4.3 Laboratory Accreditation Requirements for Major *Events*

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

*MEO*s should give preference to the use of an existing Laboratory for the analysis of *Samples*. However, in some cases, the reporting time requirements for a Major *Event* may require that a Laboratory facility be in proximity to the Major *Event* such that *Samples* can be delivered by *Doping Control* staff. This may require an existing Laboratory to establish a temporary "satellite facility" with appropriate capabilities for the Major *Event*.

In addition, an existing Laboratory's operational environment (e.g., facilities, capabilities, staff) may not be adequate for the analytical and *Sample* handling capacity necessary for a Major *Event*. This may require the expansion of a Laboratory's existing facilities, the re-location 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* for the Major *Event* shall ensure that a proper Management System is implemented to maintain the performance, security and safety required.

There shall be an agreement, sufficiently ahead of the Major *Event,* between the *MEO* 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, and the number of specific analyses (i.e., not considered as part of the routine Analytical *Testing* menu) required for the Major *Event*. The Laboratory shall be responsible for providing *WADA* with regular and timely progress reports regarding its preparations for the Major *Event.*

#### 4.3.1 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* is required. However, the Laboratory shall meet the requirements listed below in Articles 4.3.1.1 to 4.3.1.6.

All new Test Methods for the Major *Event* shall be validated at least one (1) month prior to the start of Analytical *Testing* for the Major *Event*. In addition, any changes to Test Methods, equipment or other procedures in the Management System shall also be validated and included in the Laboratory's scope of ISO/IEC 17025 accreditation prior to the start of Analytical *Testing* for the Major *Event.*

#### 4.3.1.1 Participation in *WADA* Assessment(s)

*WADA* may perform one or more assessment(s) (preferably on-site) of the Laboratory's existing facilities with the aim of evaluating the Laboratory operations and capability to provide Analytical *Testing* services for the Major *Event.*

a) The number and type of assessments (on-site, remote and/or documentary audit) will be determined by *WADA* based on the scale of the Major *Event*'s TDP and the Laboratory's progress in preparing for the Major *Event*. The assessment(s) may include analysis of a set of EQAS samples.

b) Costs related to the *WADA* assessments shall be at the Laboratory's expense.

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

i. The latest version of the *MEO'*s TDP shall be provided to assess the adequacy of the Laboratory's plans to meet the *Testing* requirements (e.g., facilities, staff, as well as Analytical *Testing* capabilities).

ii. The physical layout of the Laboratory space to ensure that there is adequate analytical and *Sample* handling capacity (based on the expected number of *Samples* and reporting deadlines), including the separation of analytical and administrative areas of the Laboratory.

iii. The Laboratory's external security including the entry and exit points which shall be restricted to authorized personnel only.

iv. The Laboratory's internal security including restricted and dedicated Laboratory controlled zones (in particular analytical area(s), the *Sample* reception/processing room and the *Sample* storage units).

*[Comment to Article 4.3.1.1: If requested by the MEO and in accordance with applicable national laws or workplace regulations, Laboratories providing Analytical Testing services during a Major Event or storing Samples collected at a Major Event should, when justified, monitor the Laboratory perimeter and the access point(s) to Sample storage room(s) (e.g., monitoring via CCTV cameras).*

v. The Laboratory's dedicated space and security measures for the "B" Sample opening procedure, including appropriate provisions to ensure the confidentiality of the *Athlete*(s).

vi. The Laboratory's IT security system, including restricted and secure central server(s), data management system (e.g., LIMS), internal network and controlled access to the internet, if applicable.

vii. The Laboratory's organizational chart for the Major *Event*, including the Laboratory staff and the planned expansion of staff, including external experts. Details shall include names, qualifications, area(s) of operation and responsibilities. In addition, the organizational chart shall identify the Certifying Scientists (internal and external experts) per Analytical *Testing* Procedure.

viii. The recruitment, training and logistics plans for the external scientists, including the names, expertise, and area(s) of responsibility for the Major *Event*.

ix. The capacity of the Laboratory's existing instrumentation and equipment including the plan and timelines to order, install and qualify additional instrumentation to meet the Analytical *Testing* requirements for the Major *Event*.

x. The capacity of the Laboratory's existing Analytical *Testing* Procedures, including plans and timelines for method development and validation to meet any additional Analytical *Testing* requirements for the Major *Event*.

xi. The Laboratory's Scope of ISO/IEC 17025 accreditation including any planned additions to the scope of accreditation.

xii. The status of the Laboratory's stock of RMs, including the plans to order, qualify and validate any new RMs and/or RCs.

xiii. The Laboratory's internal Quality Assessment Scheme (iQAS) and internal audit program, including the expansion of these programs to include new Test Methods.

xiv. The Laboratory plans and timelines for conducting "stress test(s)" to assess the performance of the Analytical *Testing* process. At least one (1) stress test shall be completed by the time the Laboratory is in its final configuration for the Major *Event*.

xv. Assessment of compliance with the ISL and its related *TD*s, *TL*s and applicable LGs.

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

i. All construction requirements are completed, including any specific measures to ensure the adequacy of the physical layout and security of the Laboratory and the "B" *Sample* opening procedure.

ii. All measures have been implemented to ensure the adequacy of the Laboratory's IT security system.

iii. All required Analytical Methods are validated and incorporated in the Laboratory's ISO/IEC 17025 scope of accreditation.

iv. All required equipment and supplies are received, including RMs and/or RCs.

v. All staff recruitment is completed, including agreements, logistics and schedules for external experts.

vi. All corrective actions from the prior *WADA* assessment have been satisfactorily addressed.

vii. The Laboratory has successfully conducted at least one (1) "stress test" to evaluate its readiness for the Major *Event*.

e) Any remaining issue(s) shall be addressed by the Laboratory before Analytical *Testing* for the Major *Event* is scheduled to begin.

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

g) An Assessment Report will be issued to the Laboratory and the Lab EAG for each *WADA* assessment. The Laboratory shall address and satisfactorily correct all noncompliances identified during the *WADA* assessment(s) and/or resulting from its analysis of EQAS samples. The documentation of the corrective actions shall be submitted to *WADA* as instructed and evaluated by *WADA* as satisfactory prior to the start of Analytical *Testing* for the Major *Event.*

#### 4.3.1.2 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 satisfactory corrective action(s) for any noncompliance(s) identified in the EQAS to *WADA*. Unsatisfactory responses shall result in disqualification of the Laboratory from performing the Analytical *Testing* for the Major *Event.*

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

#### 4.3.1.3 Pre-*Event* Report

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

a) A valid signed contract between the Laboratory and the responsible TA/*MEO* including a TDP detailing the *Sample* collection schedule, number of urine and blood *Samples* and requests for specific analyses (e.g., EPO).

b) 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.

c) A list of all senior personnel temporarily working in the Laboratory for the Major *Event* (including name, qualifications, and areas of responsibility).

d) A training plan with timelines for new staff, including temporary staff and invited external experts. The Laboratory Director shall ensure that the external personnel are adequately trained in the methods, policies, and procedures of the Laboratory. Emphasis should be given to the ISL 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.

e) A list of instrumental resources and equipment including identification of ownership.

f) A list of Analytical *Testing* Procedures within the Laboratory's Scope of ISO/IEC 17025 Accreditation and other method details as requested by *WADA*.

g) Summary Report(s) for any stress test conducted.

Any changes to the elements included in the Laboratory report shall be immediately reported to *WADA*.

#### 4.3.1.4 Additional Professional Liability Insurance Coverage

Laboratories performing Analytical *Testing* during a Major *Event* shall verify whether their professional liability risk insurance coverage is adequate to cover the liability associated with the analysis of *Samples* and the hiring of additional temporary staff during the Major *Event.* If necessary, the Laboratory shall obtain complementary professional liability risk insurance coverage.

#### 4.3.1.5 "B" Confirmations

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

a) An entry and exit plan for *Athletes*, which ensures anonymity from external attention.

b) In addition to the requirements of Article 5.3.4.2.2.3 e), a representative from *WADA* or *WADA*'s Independent Observers (IO) Team for Major *Events* (if requested by *WADA* or the IO team, respectively) shall be authorized to attend the "B" *Sample* CP.

c) The scheduling of the "B" *Sample* CP shall be made as soon as possible, in consultation with the *MEO*, and considering that postponement could significantly increase the risk of *Sample* degradation and/or inadequately delay the decision-making process in the given circumstances.

#### 4.3.1.6 Documentation and Reporting

The reporting time required for Major *Events* may be substantially less than twenty (20) days (see also Article 5.3.6.4). The agreement between the Laboratory and the *MEO* shall clarify the reporting timelines for Negative Findings, *AAF*s, *ATF*s and the reporting of specific test results (e.g., GC/C/IRMS, EPO).

### 4.3.2 Major *Event* Analytical *Testing* in "Satellite" Laboratory Facilities

In addition to the accreditation requirements for Major *Events* listed in Article 4.3.1, a Laboratory which is required to move or extend its operations temporarily to a new physical location ("satellite facility"), shall also meet the following requirements:

The "satellite facility" shall be established sufficiently in advance of the Major *Event* to allow for the timely transfer of Laboratory operations and validation of Test Methods.

#### 4.3.2.1 Participating in *WADA* Assessment(s)

*WADA* may perform an initial assessment of the Laboratory "satellite facility" as soon as it is available to determine whether the new facility is adequate in relation to the expected security, analytical and *Sample* handling requirements for a Major *Event*. Emphasis will be placed on the adequacy of security considerations, the physical layout of the space to ensure that adequate separation of various parts of the Laboratory are maintained, and to provide a preliminary review of other key support elements and to assess compliance with the ISL and ISO/IEC 17025. For further details about *WADA* assessments in preparation for a Major *Event* refer to Article 4.3.1.1.

#### 4.3.2.2 Documenting ISO/IEC 17025 Accreditation of the "Satellite Facility"

At least one (1) month prior to the start of the scheduled Analytical *Testing* for the Major *Event*, the Laboratory must provide documentation that the relevant Accreditation Body has approved the continued accreditation or accepted the suitability of the "satellite facility". An ISL trained assessor shall participate in the Accreditation Body assessment of the "satellite facility".

#### 4.3.2.3 Professional Liability Insurance Coverage

Before *WADA* grants accreditation to the "satellite" facility for Analytical *Testing* during the Major *Event*, the Laboratory shall provide documentation to *WADA* that their professional liability risk insurance covers their operations in the "satellite" facility for the analysis of *Samples* during the Major *Event.*

If necessary, the Laboratory shall obtain additional professional liability risk insurance to cover "satellite" facility operations during the Major *Event*.

#### 4.3.2.4 Obtaining a Temporary and Limited *WADA* Accreditation Certificate

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

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

c) Based on the documentation provided, *WADA* reserves the right to decide regarding accreditation of the Laboratory "satellite facility".

*d)* If 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.*

e) If the accreditation is not awarded, it is the responsibility of the TA/*MEO* to activate a contingency plan to ensure that Analytical *Testing* of *Samples* is conducted in compliance with ISL requirements during the Major *Event*.

## 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 *TD*s, *TL*s or LGs shall be governed by ISO/IEC 17025 (or ISO 15189, as applicable for *ABP* Laboratories).

This section focuses on the specific parts of the Laboratory Analytical *Testing* processes that are critical to the quality of the laboratory's performance as a Laboratory or *ABP* Laboratory and are therefore significant in the evaluation and accreditation process.

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:

a) Structural and Resource Requirements,

b) Process Requirements,

c) Management Requirements.

### 5.2 Structural and Resource Requirements

#### 5.2.1 General

General Laboratory structure and resources (personnel, facilities, equipment, metrological traceability and externally provided products and services) shall be provided and managed in accordance with the requirements of ISO/IEC 17025 (or ISO 15189, as applicable for *ABP* Laboratories) and shall be compliant with the ISL and its associated Laboratory normative documents (*TD*s, *TL*s, LGs).

#### 5.2.2 Laboratory Personnel

As applicable, Laboratory personnel shall have knowledge of their responsibilities including the security of the Laboratory, the ISL Code of Ethics, confidentiality of Analytical *Testing* results, LCOC protocols, and the Standard Operating Procedures (SOPs) for the Analytical *Testing* Procedure(s) performed.

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

##### 5.2.2.1 Laboratory Director

a) The Laboratory shall have a qualified *Person* appointed as the Laboratory Director, who is responsible for the Laboratory's professional, organizational, educational, operational, and administrative activities, and as such is recognized by *WADA*.

b) The Laboratory Director plays an essential role in the Laboratory's operations and the *WADA* accreditation or *ABP* approval of the

Laboratory is delivered based upon such qualification as well as on the Laboratory's operational performance.

c) 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.

d) The Laboratory Director is responsible for disseminating *WADA* correspondence (e.g., normative documents, instructions, EQAS or Laboratory Assessment Reports, guidance documentation) to the relevant Laboratory staff.

e) The Laboratory Director should be a full-time appointment. If the Laboratory Director holds other positions, they shall not adversely impact the Director's Laboratory responsibilities.

f) The Laboratory Director's qualifications shall include:

i. Doctoral degree (Ph.D. or equivalent) in one of the natural or life sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area; or

- In the absence of a Doctoral degree, a postgraduate degree (e.g., Master degree) in one of the natural or life sciences and appropriate laboratory experience and training (e.g., a senior laboratory position for a minimum of five (5) years), including the documented ability to develop analytical methodology and oversee research projects; or
- In the absence of a postgraduate degree, a Bachelor degree in one of the natural or life sciences and extensive and appropriate laboratory 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.

ii. Experience and competence in the analysis of chemical and biological material (preferably for the classes of substances and methods used in doping).

iii. Knowledge of drug metabolism and pharmacokinetics (preferably for the classes of substances and methods used in doping).

iv. 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 and its associated Laboratory normative documents. For non-native English speakers, proficiency should be at least at a level B2 of the European Framework of Reference for Languages (CEFR), or similar.

g) Any personnel changes to the position of Laboratory Director shall be communicated to *WADA* no later than one (1) month prior to the date scheduled for the Laboratory Director to vacate 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 or reject the candidate in accordance with the above qualifications.

#### 5.2.2.2 Laboratory Quality Management Staff

a) The Laboratory may have a single staff member appointed as the Laboratory Quality Manager or a defined Quality Management Team.

b) The Quality Manager/Management Team shall have responsibility and authority to implement and ensure compliance with the Management System. The Quality Manager/Management Team's priority and functions shall be focused on *Quality Assurance* activities. The Quality Manager/Management Team should remain independent, as much as possible, from the routine Laboratory analytical activities.

c) The Laboratory Quality Manager/Management Team members qualifications shall include:

i. At least a Bachelor degree (or similar) in one of the natural or life sciences with appropriate experience and/or training in chemical and/or biochemical sciences.

ii. Appropriate experience of two (2) years or more in laboratory analytical procedures.

iii. Appropriate documented qualifications and training in laboratory quality management, including ISO/IEC 17025 or ISO 15189, as applicable for *ABP* Laboratories.

iv. Ability to ensure compliance with the Management System and *Quality Assurance* processes.

#### 5.2.2.3 Laboratory Certifying Scientists

a) The Laboratory shall have enough qualified personnel to serve as Certifying Scientists to review all pertinent Analytical Data, Analytical Method validation results, quality control results, LDOCs and CoAs, and to attest to the validity of the Laboratory's test results.

b) Certifying Scientists shall have a thorough understanding of the Laboratory's Management System including the review, interpretation and reporting of test results, the maintenance of LCOC, and proper implementation of corrective actions in response to analytical problems.

c) The qualifications of Certifying Scientists shall include:

i. At least a Bachelor degree (or similar) in one of the natural or life sciences with appropriate experience and/or training in chemical and/or biochemical analysis, preferably in the anti-doping area.

ii. Appropriate Laboratory training and experience (e.g., three (3) years or more) including theoretical knowledge and technical competence in the analysis and interpretation of results for chemical or biological materials, including the classes of substances and/or methods used in doping.

iii. Knowledge of relevant *TD*s, *TL*s, LGs, TNs and other technical standards and relevant scientific literature.

iv. Experience in the use of relevant analytical techniques (*e.g*., chromatography, immunoassays, electrophoresis, flow cytometry, mass spectrometry) and the application/interpretation of statistical tools to the evaluation of Analytical Data.

v. Adequate training in the Laboratory's Management System and thorough understanding of its application into Laboratory processes.

### 5.2.3 Laboratory Facilities and Environmental Conditions

#### 5.2.3.1 Laboratory Facilities

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

a) 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.

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

i. Reception Zone: An initial point of controlled access into the Laboratory beyond which unauthorized individuals shall not be permitted.

- The Laboratory shall have a system to register visitors and authorized individuals into the Laboratory;
- The Laboratory shall require authorized individuals to carry an identification badge while in the Laboratory facilities.

ii. Controlled Zones: Access to these areas shall be restricted (e.g., by using 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 restricted to Laboratory staff and temporarily approved/authorized personnel (e.g., maintenance engineers, auditing teams). All other visitors to the Laboratory Controlled Zones shall be continuously escorted by Laboratory staff member(s). Access to the Laboratory Controlled Zones shall be defined in the Laboratory's Management System;
- The Laboratory shall have a dedicated area within the Controlled Zone for Sample receipt and Aliquot preparation. Access to the Laboratory's *Sample* receipt and Aliquot preparation area shall be restricted to authorized personnel, based on a risk assessment by the Laboratory;
- The Laboratory shall have a dedicated *Sample* storage area. Access to stored *Samples* [4] shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.

#### 5.2.3.2 Relocation of Laboratory Facilities

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

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

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

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

d) New Laboratory contact information and coordinates.

e) Assessment of the effect of the Laboratory relocation on client operations.

#### 5.2.3.3 Environmental Control

a) The Laboratory environmental conditions shall be in accordance with the requirements of ISO/IEC 17025 (or ISO 15189, as applicable for *ABP* Laboratories). This includes records of use of controlled chemicals and reagents, waste disposal procedures, electrical services, environmental health and safety policies, etc.

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

b) The Laboratory shall have a written risk assessment-based policy to ensure appropriate electrical service (for example, by provision of an alternative power supply such as an UPS system and/or power generators) and environmental conditions (space, temperature, humidity, as applicable) for all Laboratory instrumentation and equipment critical to Laboratory operations, such that service is not likely to be interrupted. This policy shall ensure the integrity of refrigerated and/or frozen stored *Samples* in the event of an electrical or freezer/refrigerator equipment failure.

#### 5.2.3.4 Confidentiality of Data, Information and Operations

a) The Laboratory shall implement a procedure(s) for maintaining the confidentiality of Laboratory information and operations, for the appropriate use and protection of access badges during and outside of working hours, and for addressing risks of unauthorized access by third parties.

b) The Laboratory should implement a clean desk policy and shall securely file any confidential or sensitive information or properly dispose of it.

c) To minimize any attempts of fraud or counterfeit, the Laboratory should implement a procedure to ensure that discarded urine and/or blood *Sample* containers, as well as the seals and rings, are not accessible to unauthorized *Persons* or recovered after disposal (for example, bottles should be destroyed, or trash containers should be properly secured).

#### 5.2.3.5 Control and Security of Electronic Data and Information

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

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

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

*[Comment to Article 5.2.3.5 c): The data and information management system may also feature workflow management, data tracking support, Sample and Aliquot LCOC, control of stocks of RM, etc.]*

d) The Laboratory shall utilize a secure data storage system that prevents unauthorized access and data loss (e.g., failed hard drive, fire, flooding).

e) The Laboratory shall ensure that regularly backed-up copies of all relevant analytical/LIMS/instrument software files are available (e.g., a mirrored server that guarantees the integrity of the server and the stored data).

i. If the Laboratory is utilizing a non-cloud-based system, then at least one (1) backup copy shall be stored in a restricted and secure environment either in the Laboratory (e.g., fire and waterproof safe) or in a secure off-site location.

ii. If the Laboratory is using a cloud-based system, the Laboratory data shall be, at a minimum, replicated in two (2) separate data centers (e.g., between two different availability zones within the same region or between different regions) to minimize the possibility of data loss.

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

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

### 5.2.4 Laboratory Equipment

a) The Laboratory shall operate and maintain the equipment required for the correct performance of its Analytical *Testing* Procedures in accordance with ISO/IEC 17025 requirements (or ISO 15189, as applicable for *ABP* Laboratories).

b) The Laboratory shall maintain sufficient instrumental capacity to minimize the risk of operational delays in cases of malfunctions or breakdowns and meet the analytical and results reporting obligations of the ISL and its related normative documents.

### 5.2.5 Metrological Traceability – Use and Control of Chemicals, Reagents and Reference Materials (RMs)

a) Chemicals and reagents shall be Fit-for-Purpose, be of appropriate purity and maintained in sufficient supply such that the Laboratory's Analytical *Testing* and reporting are unlikely to be interrupted.

b) Chemicals, reagents, and kits labelled "Research Only" or "Forensic Use Only", for example, may be utilized for the purposes of *Doping Control* provided they are demonstrated to be Fit-for-Purpose by the Laboratory and/or *WADA.*

c) The Laboratory shall maintain a record of reference standards utilized in Analytical *Testing* (e.g., RMs, stock and working solutions, calibrators, quality control samples) including records of traceability to original material, evaluation, and approval prior to implementation in routine operations.

#### 5.2.5.1 RMs

a) When available, RMs of substances traceable to a national standard or certified by a body of recognized status (e.g., USP, BP, Ph.Eur., WHO) or an RM producer accredited to ISO 17034 should be used.

When a RM is not a CRM, the Laboratory shall verify its identity and Fitness-for-Purpose by comparison with published or internal Laboratory data and/or by chemical characterization.

b) Where justifiable (e.g., in cases of unavailable, rare, or difficult to obtain RM or RC), the Laboratory may consider using in-house prepared RMs (in accordance with ISO Guide 80) or extending the RM expiration date 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 RM, RC, or solution shall be described in the Laboratory's Management System documentation.

*[Comment to Article 5.2.5.1 b): Such extension of the expiration date of RMs is not permitted for RMs used in the confirmatory quantification of Threshold Substances.]*

#### 5.2.5.2 RCs

Samples or isolates may be obtained from *in vitro* or *in vivo* sources for use as RCs, including:

a) An external quality control sample.

b) A past *Sample* used for *Quality Assurance* in accordance with Article 5.3.8.2.

c) An isolate from a urine or blood sample after a controlled administration.

d) An *in vitro* incubation with liver cells, microsomes or biological fluids.

RCs shall be traceable to a *Prohibited Substance* or a *Prohibited Method*, and the Analytical Data shall be sufficient to establish the identity of the Analyte.

### 5.2.6 Externally Provided Analytical Services

a) A Laboratory may request the provision of external analytical services (subcontracting of analysis) by another Laboratory, in consultation with the TA. The conditions that justify the request for external analysis include, for example:

   i) A specific technology or Analyte(s) that is not within the Laboratory's Scope of ISO/IEC 17025 Accreditation.

   ii) An ATR imposed on the Laboratory.

   iii) Other justifications such as a need for higher sensitivity or specific equipment or expertise, temporary workload, or technical incapacity.

   iv) Other specific investigations, such as, without limitation, forensic examinations which need to be performed during the Analytical *Testing* process.

   v) In exceptional circumstances, *WADA* may elect to grant specific authorization to subcontract analyses using specific Test Methods to an ISO/IEC 17025-accredited laboratory (for example, DNA analysis or genomic profiling).

   In all such cases:

   vi) *Sample* Aliquot(s), appropriately secured to ensure *Sample* integrity during transportation, may be transferred for "A" *Sample* analyses (ITP and CP, if needed). However, for any analysis to be performed on "B" *Samples*, the (re)sealed (with a *Tampering*-evident mechanism) "B" *Sample* container shall be transferred.

   vii) The Laboratory making the request for external analysis is 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.

   viii) The Laboratory making the request for external analysis shall be responsible for reporting the analytical results of the subcontracted analysis in *ADAMS*, as provided by the external provider of analytical services (subcontracted Laboratory), while specifying that the analysis was performed by the subcontracted Laboratory.

b) On occasions, the TA or *WADA* may decide to instruct a Laboratory to transfer *Sample*(s) to other Laboratory(-ies) for analysis (e.g., for Test Methods not within the Scope of ISO/IEC 17025 Accreditation of the Laboratory). In such cases, the Laboratory shall nevertheless ensure the *Sample* chain of custody in connection with the transfer of the *Sample*(s).

Recommendations to facilitate the implementation of externally provided analytical services are provided in the *WADA* LGs on "Conducting and Reporting Externally Provided Analytical Services and Further Analysis for *Doping Control*".

## 5.3 Process Requirements

The Laboratory shall maintain paper or electronic LCOC in compliance with the *TD* LCOC.

### 5.3.1 Reception, Registration and Handling of *Samples*

a) The Laboratory may receive *Samples*, which have been collected, sealed, and transported to the Laboratory in compliance with the *International Standard* for *Testing* (IST).

b) The transfer of the *Samples* from the courier or other *Person* to the Laboratory shall be recorded including, at a minimum:

i. The date.

ii. The time of receipt.

iii. The initials or (electronic) signature of the Laboratory representative receiving the *Samples* and the courier company tracking number, if available.

iv. This information shall be included in the LCOC record(s) of the *Sample(s).*

c) The *Sample* transport container shall be inspected, and identified irregularities recorded *(*see Article 5.3.2.1].

d) Each individual *Sample* shall be inspected, and identified irregularities recorded *(*see Article 5.3.2.1). However, *Samples* transferred for long-term storage purposes are not subject to an individual inspection by the receiving Laboratory until a *Sample* has been selected for Further Analysis.

e) 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.

### 5.3.2 Acceptance of *Samples* for Analysis

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

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

*[Comment to Article 5.3.2 a): 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).]*

b) 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 measured by the Laboratory:

*[Comment to Article 5.3.2 b): The Laboratory may conduct analyses on the additional Samples, if deemed necessary, with the agreement of the TA. The Laboratory may also combine Aliquots from multiple Samples, if necessary, to have sufficient volume to perform the required Analytical Testing Procedure(s).*

*With the agreement of the TA, the Laboratory may store the additional, non-analyzed Samples for Further Analysis.]*

c) If a *Sample* meets documented *Sample* rejection criteria, which have been accepted by the TA (see also Article 5.3.2.1).

d) DBS *Samples* collected with urine and/or venous blood *Samples* during the same *Sample* Collection Session, provided that the TA has requested via *ADAMS* and in advance that the Laboratory put the DBS *Samples* in storage without initial analysis, and that the *Athlete* has consented to the collection of the DBS *Sample* for storage and possible future analysis without first being subject to an Analytical *Testing* Procedure.

In those cases, the Laboratory shall report the DBS *Sample* as Not Analyzed in *ADAMS* (see Article 5.3.6.4.1) until such a time that the DBS *Sample* is analyzed and the *ADAMS Sample* record is updated accordingly.

e) Except as provided in this Article 5.3.2, urine and/or venous blood *Samples* from a *Signatory* shall not be accepted by a Laboratory for the sole purpose of long-term storage or for later analysis without first being subject to an Analytical *Testing* Procedure.

#### 5.3.2.1 *Samples* with Irregularities

a) The Laboratory shall observe and document conditions that exist at the time of *Sample* reception or registration that may adversely impact on the integrity of a *Sample* or on the performance of Analytical *Testing* Procedures (with the exception of the situation when a large number of *Samples,* which have already been analyzed, are received for long-term storage only (e.g*.,* from a *MEO*] (see Article 5.3.7.1)).

b) Only unusual conditions shall be recorded. Irregularities to be noted by the Laboratory may include, but are not limited to:

i. Inadequate *Sample* transportation conditions, which may impact the integrity of the *Sample*, for example:

- Long delivery time;
- *Samples* exposed to high temperatures;
- Blood *Samples* received frozen or clotted;
- Damaged transportation packages;

- Missing “A” or “B” *Samples*;
- “A” or “B” *Sample* broken, empty, damaged or leaking;
- Issues with temperature logger, e.g., not working, not started, has stopped, or is absent (when applicable).

ii. Issues with *Sample* collection documentation and labelling, for example:

- Mismatch between the seal on the *Sample* transportation package or the *Sample* identification number on the DCF and the *Sample* container's code;
- *Sample* cap and container codes do not match;
- Absence of barcodes on *Sample* container;
- *Sample* identification numbers are different between the “A” and the “B” *Sample* containers of the same *Sample*;
- *Sample* collection documents such as chain of custody or DCF include mistakes, are incomplete or missing;
- *Athlete*’s identity information is provided in the Laboratory copy of the DCF or any other document transferred to the Laboratory;
- The test menu requested is incompatible with the *Sample* matrix.

iii. Unusual Sample conditions, for example:

- Color, odor, presence of turbidity or foam in a urine *Sample*; color, signs of hemolysis, 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* (see *TL*14);
- Insufficient *Sample* volume;
- Incorrect *Sample* matrix (e.g., blood *Samples* collected in EDTA instead of serum tubes);
- *Sample* volume does not meet the Suitable Volume of Urine for Analysis or is otherwise inadequate to perform the requested Analytical *Testing* menu;
- The Laboratory cannot open the *Sample* container;
- *Tampering* or adulteration of the *Sample* is evident;
- *Sample* is not properly sealed with *Tampering*-evident device.

c) The Laboratory shall inform and seek instructions from the TA on the performance of Analytical *Testing* on a *Sample* with irregularity(-ies). The TA shall inform the Laboratory in writing within seven (7) days whether a *Sample* with noted irregularity(-ies) shall be analyzed or not,

and/or of any further measures to be taken (e.g., splitting the *Sample* in accordance with Article 5.3.2.2, forensic analysis, DNA analysis), or that the *Sample* should be stored for Further Analysis. The communication between the Laboratory and the TA shall be recorded as part of the *Sample*'s documentation.]

d) Whether a *Sample* with noted irregularities is analyzed or not following the TA instructions, the Laboratory shall record any irregularities that impact the *Sample*'s chain of custody or integrity in *ADAMS*.

#### 5.3.2.2 *Sample* Splitting Procedure

The Laboratory shall have a procedure to split a *Sample* as described below.

a) In cases when either the "A" or "B" *Sample* is not suitable for the performance of the analyses, the Laboratory shall notify and seek authorization from the TA to split the other *Sample* container ("A" or "B", as applicable), provided that it is properly sealed. Conditions that may require a *Sample* splitting procedure include, but are not limited to:

   i. Insufficient *Sample* volume.

   ii. The *Sample* container has not been properly sealed or has been broken.

   iii. The *Sample*'s integrity has been compromised in any way.

   iv. The *Sample* is heavily contaminated.

   v. The "A" or "B" *Sample* is missing.

b) The TA shall inform the Laboratory of its decision in writing within seven (7) days of notification by the Laboratory. If the TA decides not to proceed with the Sample splitting procedure, then the Laboratory shall report the *Sample* as "Not Analyzed" in *ADAMS*, including the noted *Sample* irregularities and the documented reasons if provided by the TA.

c) The process of opening and splitting the *Sample* and resealing of the remaining second fraction shall be conducted in accordance with Article 5.3.4.2.2.3 g) as conducted for a routine "B" *Sample* opening, including:

   i. 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.

   ii. If the *Athlete* cannot be located, does not respond or the *Athlete* and/or his/her representative does not attend the opening and splitting of the *Sample*, the procedure shall be done in the

presence of an Independent Witness that is assigned by the Laboratory.

*[Comment to Article 5.3.2.2. c): If the Athlete chooses to witness the Sample splitting procedure, the Athlete takes responsibility for forfeiting their anonymity.]*

d) When the splitting procedure concerns blood *Samples*, which have been collected for Analytical *Testing* on the blood serum/plasma fraction, the sealed, intact ("A" or "B") *Sample* shall be centrifuged as soon as practical after Laboratory reception to obtain the serum or plasma fraction.

   i. The centrifuged *Sample* shall be stored frozen in the sealed *Sample* collection tube according to established protocols until the *Sample* opening/splitting procedure can be conducted.

   ii. 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.

e) The first fraction of the split *Sample* shall be considered as the "A" *Sample* and shall be used for the ITPs, unless the ITPs have already been performed, and/or the "A" CPs, if necessary. The second fraction, considered as the "B" *Sample*, shall be resealed, and stored frozen for "B" CPs, if necessary.

### 5.3.3 Initial Storage and *Sample* Aliquoting for Analysis

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

b) The Aliquot preparation area and procedure for the ITP or CP shall minimize the risk of contamination of the *Sample* or Aliquot.

c) The Laboratory shall use new material(s) (e.g., new test tubes) to take Aliquots for CPs.

#### 5.3.3.1 Urine *Samples*

a) To maintain the stability and integrity of the urine *Samples*, the Laboratory shall implement *Sample* storage procedures that minimize exposure to room and refrigerated temperatures as well as *Sample* freeze/thaw cycles.

b) The Laboratory shall obtain, following proper homogenization of the *Sample*, an initial Aliquot containing enough *Sample* volume to perform all analytical procedures (all ITPs or all intended CPs, as applicable), by decanting the Aliquot from the urine *Sample* container into a secondary container (e.g., a Falcon tube). The procedure-specific Aliquot(s) shall then be taken from the secondary container.

c) The Laboratory shall measure the pH and SG of urine *Samples* once, using one Aliquot, during the ITP and the CPs ("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 *TD* EAAS).

d) Urine "A" *Samples* should be frozen after Aliquots are taken for the ITPs to minimize the risk of *Sample* microbial degradation.

e) Urine "B" *Samples* shall be stored frozen, as soon as possible, after reception until analysis, if applicable.

#### 5.3.3.2 (Venous) Blood *Samples*

a) The Laboratory shall follow the applicable *TD*s*, TL*s or LGs for handling and storing blood *Samples*.

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

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

- Blood *Samples* ("A" and "B" *Samples*), for which Analytical *Testing* will be performed on the plasma/serum fraction only shall be centrifuged, as soon as practical, after Laboratory reception to obtain the serum or plasma fraction [5];
- The "A" *Sample* serum or plasma fraction (contained in the "A" *Sample* collection tube) and/or the "A" *Sample* serum or plasma Aliquots taken from the *Sample* into separate vials may be stored refrigerated for a maximum of 24 hours (but not surpassing the maximum allowed time from *Sample* collection established in the applicable *TD*, *TL* or LGs) or frozen until analysis;
- "A" *Sample* serum or plasma Aliquots used for "A" CPs shall be analyzed as soon as possible, but no later than twenty-four (24) hours after thawing;
- Following centrifugation, the "B" *Sample* serum or plasma fractions shall be stored frozen in the *Sample* collection tube according to established protocols (which minimize the contamination of the serum or plasma fractions with red blood cells lysed upon thawing) until analysis, if applicable [5];
- Following the conclusion by the Laboratory of a PAAF in the "A" *Sample*, the Laboratory shall transfer the corresponding "B" *Sample* tube to freezing at -70 °C or less;

[5] Unless otherwise specified in a *TD*, *TL* or LGs.

- "B" *Sample* plasma or serum Aliquots shall be analyzed within twenty-four (24) hours after thawing. The remaining "B" *Sample* shall be returned to storage at -70°C or less.

ii. *Samples* for which Analytical *Testing* will be performed on the cellular fraction of whole blood.

- Whole blood *Samples* shall be maintained refrigerated and shall be analyzed according to established protocols;
- After Aliquots have been taken for analysis, *Samples* shall be returned to refrigerated storage. Whole blood *Samples* shall not be frozen;
- If additional analyses (e.g., EPO) are to be performed on the plasma fraction of the whole blood *Sample*, the *Sample* centrifugation and additional analysis shall await the completion of the analyses [including the ITPs, and any applicable "A" and/or "B" CPs] on the cellular components of whole blood. Then, the plasma fraction of the *Sample* shall be obtained and processed as described above.

#### 5.3.3.3 Dried Blood Spot (DBS) *Samples*

DBS *Sample* storage and aliquoting shall follow the directives from the *TD* DBS [2], or other applicable *TD*, *TL* or LGs.

### 5.3.4 Analysis of *Samples*

#### 5.3.4.1 Selection and Validation of Analytical *Testing* Procedures

a) The Laboratory shall use Analytical *Testing* Procedures that are Fit-for-Purpose, as demonstrated through method validation, for the analysis of representative target Analytes of *Prohibited Substances* and *Prohibited Methods*.

b) Validation results for Analytical *Testing* Procedures shall be summarized in a Validation Report and supported by the necessary documentation and Analytical Data.

For more details on Analytical *Testing* Procedure validation requirements, refer to the *TD* VAL.

#### 5.3.4.2 S*ample* Analysis

a) The Laboratories shall employ only validated, Fit-for-Purpose Analytical *Testing* Procedures documented in the Laboratory's Management System (e.g., SOPs) to the analysis of *Samples*.

b) The Laboratory shall analyze *Samples* collected by *ADO*s or *DTP*s using *IC* or *OOC* Analytical *Testing* menus, as applicable, to detect the presence of *Prohibited Substances* or *Prohibited Methods* only (as defined in the *Prohibited List*).

*[Comment to Article 5.3.4.2 b): An ADO, at its discretion, may apply anti-doping rules to an Athlete who is neither an International-Level Athlete nor a National-Level Athlete and may elect to request that Samples collected from these Athletes are analyzed for less than the full menu of Prohibited Substances and Prohibited Methods. The Anti-Doping Organization is responsible for providing the Laboratory with the appropriate written justification for a reduced Testing menu.]*

c) In addition, the Laboratory may analyze *Samples* for the following, in which case the results of the analysis shall not be reported as an *ATF* or an *AAF*:

i. Non-prohibited substances or methods that are included in the *WADA* Monitoring Program (see *Code* Article 4.5).

ii. Non-prohibited substances for results interpretation purposes (e.g., confounding factors of the "steroid profile", non-prohibited substances that share *Metabolite(s)* or degradation products with *Prohibited Substances*), if applicable.

iii. Non-prohibited substances or methods (including substances prohibited *IC* only and analyzed in *Samples* collected *OOC*) if requested as part of a *Results Management* process by the RMA, a hearing body or *WADA*.

iv. Non-prohibited substances or methods requested by the TA as part of its safety code, code of conduct or other regulations (see comments to *Code* Articles 5.1 and 23.2.2), or

v. Additional analyses for research or *Quality Assurance* in accordance with the requirements indicated in Article 5.3.8.2.

d) At minimum, the Laboratory is required to implement all mandatory Analytical *Testing* Procedures, as determined by *WADA* in specific *TD*s, *TL*s or LGs. The Laboratory may implement additional methods for the analysis of particular *Prohibited Substances* or *Prohibited Method*s.

*[Comment to Article 5.3.4.2 d): Mandatory Analytical Testing Procedures are those Analytical Methods for which the Laboratory shall have available analytical capacity, in compliance with relevant TDs, TLs or LGs, and therefore should have the Analytical Method included in their Scope of ISO/IEC 17025 Accreditation. However, based on an IC or OOC Analytical Testing menu, a mandatory Analytical Testing Procedure is not necessarily applied to all Samples. For some Prohibited Substances or Prohibited Methods, the TA may decide to request their analysis in specific Samples only. These requests shall be detailed in the Sample chain of custody. WADA will maintain the list of mandatory Analytical Testing Procedures for reference by the Laboratories and ADOs.]*

e) Analytical *Testing* Procedure(s) included in the Laboratory's Scope of ISO/IEC 17025 Accreditation (or ISO 15189, as applicable for *ABP* Laboratories) shall be considered as Fit-for-Purpose and therefore the Laboratory shall not be required to provide method validation documentation or EQAS performance data in support of a Test Result.

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 *TD*s, *TL*s or LGs prior to its application to the analysis of *Samples*. In such cases, the Laboratory may be required to provide method validation documentation or EQAS performance data in support of an *AAF* (see Article 4.1.4.2.4).

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

#### 5.3.4.2.1 Application of Initial *Testing* Procedures (ITPs)

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

b) Results from ITPs can be included as part of longitudinal studies (e.g., endogenous steroid, endocrine or hematological profiles), provided that the method is Fit-for-Purpose.

c) The ITPs shall fulfil the following requirements:

i. Performed on Aliquot(s) taken from the container identified as the "A" *Sample*.

*[Comment to Article 5.3.4.2.1 c): In cases when the "A" Sample cannot be used for the ITPs, the ITPs may be performed on an Aliquot of the first bottle of the split "B" Sample, which is to be used as the "A" Sample (see Article 5.3.2.2).]*

ii. Be recorded, as part of the *Sample* (or *Sample* batch) record, each time it is conducted.

iii. Include appropriate negative and positive quality controls (QCs) prepared in the matrix of analysis, in accordance with its method validation results (see *TD* VAL) [6].

iv. The Laboratory shall establish criteria, based on its method validation results, to evaluate results from an

[6] Unless otherwise specified in a *TD*, *TL*, or LGs.

ITP as a PAAF, which would trigger confirmation analyses.

v. Results from ITPs are not required to consider the associated MU [6].

vi. Irregularities in the ITPs shall not invalidate an *AAF*, which is adequately established by a CP.

#### 5.3.4.2.2 Application of Confirmation Procedures (CP)

a) The objective of the CP is to obtain a result, which supports or does not support the reporting of an *AAF* or *ATF*.

b) A CP for a Non-Threshold Substance with an *MRL* may also be performed if the result estimated from the ITP is lower than the applicable *MRL*, as determined by the Laboratory in accordance with the method's validation results.

c) A CP for a Threshold Substance may also be performed if the result estimated from the ITP is lower than the applicable *DL*, as determined by the Laboratory in accordance with the method's validation results or as specifically required by the TA (or RMA, if different) or *WADA* [7].

d) The CP(s) shall fulfil the following requirements:

i. Be recorded, as part of the *Sample* (or *Sample* batch) record, each time it is conducted.

ii. Have equivalent or greater Selectivity than the ITP and, when applicable, shall provide accurate quantification results, including the estimation of the associated MU.

iii. Incorporate, when possible and adequate, a different *Sample* extraction protocol and/or a different analytical methodology [7].

iv. Include appropriate negative and positive QCs prepared in the matrix of analysis, in accordance with its method validation results (see *TD* VAL) and applicable *TD*s, *TL*s or LGs.

[7] Unless otherwise specified in a *TD*, *TL*, or LGs.

#### 5.3.4.2.2.1 CP Methods

a) Mass spectrometry (MS) coupled to chromatographic separation (e.g., gas or liquid chromatography) is the analytical technique of choice in anti-doping analysis. These are suitable methods for both the ITP and the CP.

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

i. Affinity-binding assays applied for the ITPs and CPs shall use affinity reagents (e.g., antibodies) recognizing different epitopes of the macromolecule analyzed, unless a Fit-for-Purpose 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.

ii. In affinity-binding assays which include multiple affinity reagents (such as sandwich immunoassays), at least one (1) of the affinity reagents (either applied for capture or detection of the target Analyte) used in the affinity-binding assays applied for the ITPs and CPs must differ. The other affinity reagent may be used in both affinity-binding assays.

iii. 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 analytical approaches may be used.

iv. Antibodies may also be used for specific labelling of cell components and other cellular characteristics.

*[Comment to Article 5.3.4.2.2.1 b): 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 AAF replaces the requirement for two (2) antibodies recognizing different antigenic epitopes. An example is the detection of surface Markers on red blood cells (RBCs) using flow cytometry. The flow cytometer is set up to selectively recognize RBCs. The presence on the RBCs of more than one surface Marker (as determined by antibody labelling) as a criterion for an AAF may be used as an alternative to multiple antibodies to the same Marker.]*

#### 5.3.4.2.2.2 "A" CP

a) Aliquots

i. The "A" CP shall be performed using new Aliquot(s) taken from the container identified as the "A" *Sample*.

ii. At this point, the link between the *Sample* external code as shown in the *Sample* container and the Laboratory internal *Sample* code shall be verified.

*[Comment to Article 5.3.4.2.2.2 a): In cases when the "A" Sample cannot be used, the "A" CP may be performed on an Aliquot of the split "B" Sample (see Article 5.3.2.2).]*

b) Target Analyte(s)

i. If the presence of more than one (1) *Prohibited Substance*, *Metabolite(s)* or *Marker(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use* of *Prohibited Method* is detected by the ITPs, the Laboratory shall confirm as many of the PAAFs as reasonably possible.

ii. Such decision shall be made in consultation with the TA (or RMA, if different) and documented, and should consider the following:

- Existence or not of an approved *TUE*, as confirmed by the TA in writing (see point c. below);
- Prioritization of the identification and/or quantification of the *Prohibited Substance(s)* or *Prohibited Method(s)* that carry the longest potential period of

*Ineligibility* (non-specified substances and methods);

- Volumes available in the "A" and "B" *Samples*;
- Costs of analyses (although this shall not be the main criterion for selecting which PAAF to confirm).

iii. The TA (or RMA, if different) shall inform the Laboratory which PAAF shall be subjected to CP in writing and within seven (7) days of being consulted by the Laboratory. In the absence of such timely information from the TA (or RMA, if different), the Laboratory shall proceed to confirm as many of the PAAFs as reasonably possible (while considering the criteria listed above) and invoice the TA for the costs of the analyses accordingly.

c) Existence of approved *TUE*

i. The Laboratory may contact the TA (or RMA, if different), in writing, to enquire whether an approved *TUE* exists (for further guidance, refer to the LGs on *TUE* enquiries) when there is a PAAF for:

- hCG;
- hGH (Biomarkers Test);
- Beta-2 Agonists;
- Diuretics;
- Amfetamine;
- Methylphenidate;
- Glucocorticoids; or
- Beta-blockers.

*[Comment 1 to Article 5.3.4.2.2.2 c): The selection of substances for TUE enquiries above is based on criteria such as prevalence of medical use or the non-mandatory status of the CP for Laboratories.*

*Unless there is a prior agreement between the TA (or RMA, if different) and the Laboratory, contacting the TA (or RMA, if different) in such cases is not a requirement for the Laboratory. The Laboratory may proceed, at its discretion, to confirm the PAAF for any of these*

*substances and report an AAF in ADAMS according to the confirmation results obtained. However, the Laboratory shall consult the TA (or RMA, if different) about the existence of an approved TUE if the Laboratory does not have a validated CP included in its Scope of ISO/IEC 17025 Accreditation and has to subcontract the confirmation analysis to another Laboratory, in which case the TA would have to assume the additional costs for the shipment of the Sample to the subcontracted Laboratory.]*

[*Comment 2 to Article 5.3.4.2.2.2 b): In principle, the enquiry by Laboratories regarding the existence of an approved TUE for a Beta-2 Agonist may be applied not only to those Beta-2 Agonists which are prohibited under any condition, but also to those which are permitted up to a maximum dose by inhalation only, as specified in the Prohibited List. In such cases, the Laboratory may enquire about the existence of an approved TUE for the Use of a prohibited route of administration or a supra-therapeutic inhalation dose.]*

ii. When possible, the Laboratory should provide an estimated concentration of the Analyte(s) from the ITP.

iii. The instruction by the TA (or RMA, if different) on whether the Laboratory shall proceed or not with the CP, based on an approved *TUE,* shall be provided to the Laboratory in writing (for further guidance, refer to the Laboratory Guidelines on *TUE* enquiries).

iv. The Laboratory shall follow the written instructions from the TA (or RMA, if different) on whether to proceed with the confirmation analysis.

v. If not proceeding with the confirmation, then the TA (or RMA, if different) shall provide *WADA* with a copy of the approved *TUE* or the associated *TUE* number if the *TUE* has been submitted into *ADAMS*.

d) Repetition of the "A" CP

i. The Laboratory may repeat the CP for an "A" *Sample*, if appropriate, (*e.g.*, QC failure, chromatographic peak interferences, inconclusive results). The

reasons that may lead to a repeat CP shall be described in the Laboratory's Management System documentation and included in the LDOC.

ii. In that case, the previous test result(s) shall be nullified.

iii. Each repeat "A" CP shall be recorded and shall be performed using (a) new Aliquot(s) taken from the container of the *Sample* designated as "A" *Sample*, unless the Laboratory can justify and document valid reasons for using the remains of a previously prepared "A" Aliquot.

*[Comment to Article 5.3.4.2.2.2 d): As explained in Article 5.3.2.2, the "A" CP may be performed on Aliquot(s) taken from a split "B" Sample if there is not enough volume left in the original "A" Sample container.]*

e) "A" CP for Non-Threshold Substances

i. For Non-Threshold Substances without *MRL*, *AAF* or *ATF* decisions for the "A" *Sample* shall be based on the identification of the Non-Threshold Substance or its characteristic *Metabolite(s)* or *Marker(s)*, as applicable, in compliance with the *TD* IDCR and/or other relevant *TD*, *TL* or LGs.

ii. For Non-Threshold Substances with *MRL* (as specified in the *TD* MRPL), the Laboratory shall report a "A" *Sample* as an *AAF* if the Non-Threshold Substance is identified in compliance with the *TD* IDCR, at an estimated concentration greater than the *MRL* and in compliance with the requirements of the *TD* MRPL.

The Laboratory may report a *Sample* containing a Non-Threshold Substance with an estimated concentration below the *MRL* as an *AAF* if the Non-Threshold Substance is identified in compliance with the *TD* IDCR and the *TD* MRPL and, in addition, there are other reasons for the reporting, for example:

- Indications of the *Use* of the *Prohibited Substance* (e.g.*,* the *Athlete* declared it in the DCF);
- A justification to do so as provided by the TA (or RMA, if different) or *WADA* (*e.g.*, if the analysis is part of an ongoing investigation).

f) "A" CP for Threshold Substances

i. For Threshold Substances, *AAF* or *ATF* decisions for the "A" *Sample* shall be based on:

- The confirmed identification (in accordance with the *TD* IDCR, applicable to CPs based on chromatography-mass spectrometry) of the Threshold Substance and/or its *Metabolite(s)* or *Marker(s)*; and
- A quantitative determination in the *Sample* at a level exceeding the value of the applicable *DL*, which is specified in the *TD DL* or other applicable *TD*s (e.g., *TD* GH) or LGs.

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

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

*Metabolite(s)* in the *Sample* is sufficient to conclude an *AAF*.

- For endogenous Threshold Substances, *Markers* of the "steroid profile", or any other *Prohibited* Substance that may be produced endogenously, *AAF* decisions for the "A" *Sample* may also be based on the application of any Fit-for-Purpose CP that establishes the exogenous origin of the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* (e.g., GC/C/IRMS).

  *ATFs* may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s).*

ii. Quantitative CPs for Threshold Substances shall be based on:

- The determination of the mean of measured analytical values (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) of three (3) "A" *Sample* Aliquots [8]. If there is not enough *Sample* volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

#### 5.3.4.2.2.3 "B" CP

a) *Testing* Laboratory

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

[8] Unless otherwise specified in a *TD*, *TL*, or LGs.

b) Notification of "B" CP

i. The Laboratory shall only perform the "B" CP upon written request from the relevant RMA.

ii. The RMA should inform the Laboratory, in writing, within fifteen (15) days following the reporting of an "A" *Sample AAF* by the Laboratory, whether the "B" CP shall be conducted (based on the *Athlete's* request or when the *Athlete* does not request the "B" *Sample* analysis or expressly or implici*tl*y waives his/her right to the analysis of the "B" *Sample*, but the RMA decides that the "B" CP shall still be performed).

c) Timing of "B" CP

i. It is recommended that, if requested by the RMA, the "B" CP is performed within one (1) month of reporting the *AAF* for the "A" *Sample*.

ii. The timing of the "B" CP may be strictly fixed within a very short period and without any possible postponement if circumstances justify it. This can notably and without limitation be the case when a postponement of the "B" *Sample* analysis could significantly increase the risk of *Sample* degradation and/or inadequately delay the decision-making process in the given circumstances (e.g., and without limitation, during or in view of a Major *Event* requiring rapid completion of the *Sample* analysis).

The RMA or *WADA*, as applicable, shall instruct the Laboratory to proceed if:

- The *Athlete* declines to be present in person and/or through a representative, or does not indicate whether they request the "B" *Sample* analysis; or
- The *Athlete* will not attend (in person and/or through a representative) once a date and time for the analysis has been proposed; or

- 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.

d) Independent Witness

i. The Laboratory, in consultation with the RMA or *WADA*, as applicable, shall appoint an Independent Witness to verify that:

- The "B" *Sample* container shows no signs of *Tampering;* and
- The identifying "B" *Sample* container code matches the relevant *Sample* collection documentation.

ii. An Independent Witness may be appointed even if the *Athlete* has indicated that they will be present and/or represented.

e) Non-Laboratory *Persons* that shall be authorized to attend the "B" CP

i. The *Athlete* and/or representative(s) of the *Athlete*

- The *Athlete* and a maximum of two (2) representatives, and/or the Independent Witness, have the right to attend the "B" *Sample* opening, aliquoting and resealing procedures;
- The *Athlete* and/or one (1) representative may also have reasonable opportunity to observe other steps of the "B" CP, as long as their presence in the Laboratory does not interfere with the Laboratory's routine operations or Laboratory safety or security requirements.

ii. An Independent Witness (in the absence of the *Athlete* and/or representative(s)).

iii. A translator (if applicable).

iv. A representative of the RMA (if requested by the RMA).

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

vi. The Laboratory Director may limit the number of individuals in Controlled Zones of the Laboratory based on safety or security considerations.

f) Non-Laboratory *Person* conduct during the "B" CP

i. *Persons* attending shall not interfere with the "B" *Sample* opening or the "B" CP process in any way at any time and shall strictly follow the instructions of the Laboratory.

ii. 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.

iii. Any behavior resulting in removal shall be reported to the RMA.

iv. Interference may further be constitutive of an anti-doping rule violation in accordance with *Code* Article 2.5, "*Tampering*, or *Attempted Tampering* with any part of *Doping Control* by an *Athlete* or other *Person*".

g) Opening, Aliquoting and Resealing of "B" *Sample*

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

*[Comment to Article 5.3.4.2.2.3 g): In cases when the "B" Sample cannot be used for Analytical Testing, the unopened, sealed "A" Sample may be split (see Article 5.3.2.2). The "B" CPs, if needed,*

*may be performed on an Aliquot taken from the split, resealed "A" Sample fraction that had been designated as the "B" Sample.]*

ii. The *Athlete* and/or his/her representative(s) or the Independent Witness shall verify that the "B" *Sample* container:

- Is properly sealed; and
- Shows no signs of *Tampering*; and
- The "B" *Sample* container code matches the relevant *Sample* collection documentation.

iii. At a minimum, the Laboratory Director or representative and the *Athlete* or their representative(s) and/or the Independent Witness shall sign the Laboratory documentation attesting that the "B" *Sample* container was properly sealed and showed no signs of *Tampering*, and that the identifying code matches the *Sample* collection documentation.

- If the *Athlete*, and/or their representative(s), or the Independent Witness refuses to sign the Laboratory documentation because they consider that the "B" *Sample* container was not properly sealed and/or showed signs of *Tampering*, or if the identifying numbers did not match those on the *Sample* collection documentation, the Laboratory shall not proceed with the "B" CP and shall inform the RMA immediately to obtain instructions. In such cases, the "B" CP may have to be re-scheduled.
- If the *Athlete* and/or their representative(s), or the Independent Witness refuses to sign the Laboratory documentation for any other reason, the Laboratory shall proceed with the "B" CP. In addition, the Laboratory shall inform the RMA immediately. The reason(s) for the refusal shall be documented and included as a

comment in the Test Report in *ADAMS*.

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

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

vi. At a minimum, the Laboratory Director or representative and the *Athlete* and/or their representative(s) and/or the Independent Witness shall also sign another part of the Laboratory documentation attesting that they have witnessed the "B" *Sample* opening and aliquoting procedures and that the "B" *Sample* was properly resealed.

vii. If the *Athlete* and/or their representative or the Independent Witness refuse to sign this part of the Laboratory documentation, the reasons for the refusal shall be documented and included as a comment in the Test Report in *ADAMS*. In either case, the Laboratory shall continue with the "B" CP.

h) Target Analyte(s)

If more than one (1) *Prohibited Substance*, *Metabolite(s)* or *Marker(s)* of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Method* has been confirmed in the "A" CP, the Laboratory shall confirm as many of the *AAFs* as possible given the "B" *Sample* volume available.

i. 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*.

ii. The decision should be made in consultation with the RMA and documented in writing.

i) Repetition of the "B" CP

i. The Laboratory may repeat the "B" CP, if appropriate (*e.g*., quality control failure, chromatographic peak interferences, inconclusive "B" confirmation results). The reasons that may lead to a repeat CP shall be described in the Laboratory's Management System documentation and included in the LDOC.

In that case, the previous test result shall be nullified.

ii. The Laboratory may repeat the "B" CP using the remaining volume of the same Aliquot initially taken from the "B" *Sample* container.

However, if there is not enough volume left of the initial Aliquot, then the Laboratory shall use a new Aliquot(s) taken from the re-sealed B" *Sample* container. In such cases, the re-opening, aliquoting and re-sealing of the B" *Sample* container shall be performed in the presence of the *Athlete* and/or *Athlete*'s representative(s) and/or Independent Witness, as per the procedure described above.

iii. Each Aliquot used shall be documented.

j) "B" CP with Negative Results

i. If the final "B" confirmation results are negative, the Analytical *Testing* result shall be considered a Negative Finding.

ii. The Laboratory shall notify the RMA and *WADA* immediately.

iii. 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 RMA and *WADA* within seven (7) days.

*[Comment to Article 5.3.4.2.2.3 j): Target Analytes (e.g., parent compound, Metabolite(s), Marker(s)) used to conclude the presence of a given Prohibited Substance or Use of a Prohibited Method may differ between the "A" and "B" CPs. 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.*

*A failure of a "B" CP to confirm the "A" Sample AAF does not necessarily mean that the "A" Sample result is incorrect. This discrepancy between the "A" and "B" Sample results may occur, for example, in cases of substance degradation during "B" Sample storage.]*

k) "B" CP for Non-Threshold Substances and Exogenous Threshold Substances

i. For Non-Threshold Substances (including those with *MRL* as specified in the *TD* MRPL) and exogenous Threshold Substances, the "B" *Sample* results shall only confirm the presence of the *Prohibited Substance(s)* or its *Metabolite(s)* or *Marker(s)* identified in the "A" *Sample* (in compliance with the *TD* IDCR or other applicable *TD, TL* or LGs) for the *AAF* to be valid.

ii. Quantification or estimation of concentrations of such *Prohibited Substance*, or its *Metabolite(s)* or *Marker(s)* in the "B" *Sample* is not necessary.

l) "B" CP for Endogenous Threshold Substances

i. For endogenous Threshold Substances, *AAF* decisions for the "B" *Sample* results shall be based on:

- The confirmed identification (in accordance with the *TD* IDCR, applicable to CPs based on chromatography-mass spectrometry)

of the Threshold Substance or its *Metabolite(s)* or *Marker(s);* and

- A quantitative determination in the "B" *Sample* at a level exceeding the value of the relevant *DL*[9] as specified in the *TD DL* or other applicable *TD*s or LGs.
- Comparison of the measured value of the "B" *Sample* to the measured value of the "A" *Sample* is not necessary to establish the "B" *Sample* confirmation.
- For endogenous Threshold Substances, *Markers* of the "steroid profile", or any other *Prohibited Substance* that may be produced endogenously, *AAF* 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). *ATFs* may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s).*

ii. Quantitative "B" CPs for endogenous Threshold Substances shall be based on:

- The determination of the mean of measured analytical values (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) of three (3) "B" *Sample* Aliquots [10].
- If there is not enough *Sample* volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

[9] Thresholds for endogenous Threshold Substances have been established based on reference population statistics and already incorporate a guard band that reflects the uncertainty of the measurements. Therefore, the Threshold constitutes the *DL*. The assay MU shall not be added to the test result for reporting an *AAF* or an *ATF*.

[10] Unless otherwise specified in a *TD*, *TL*, or LGs.

### 5.3.4.3 Further Analysis

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

a) Selection of *Samples* and Laboratories for Further Analysis

i. Stored *Samples* may be selected for Further Analysis at the discretion of the TA.

*WADA* may also direct the Further Analysis of *Samples* at its own expense (see *Code* Articles 6.5 and 6.6). In cases where *WADA* takes physical possession of a *Sample(s)*, it shall notify the TA (see *Code* Article 6.8).

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

iii. There is no limitation on the TA or *WADA* (or others authorized by either of them) to conduct Further Analysis on a *Sample* that has been reported as a Negative Finding or *ATF*.

iv. The Laboratory may perform Further Analysis on a stored *Sample* reported as an *AAF* if the report did not result in an anti-doping rule violation charge under *Code* Article 2.1. Any *Prohibited Substance* or *Prohibited Method* detected, which was prohibited at the time of *Sample* collection, shall be reported.

*[Comment to Article 5.3.4.3 a): Pursuant to Code Article 6.5, Further Analysis may not be applied on a Sample after the responsible ADO has charged the Athlete with a Code Article 2.1 anti-doping rule violation, and before the case is finally resolved, without the consent of the Athlete or approval from a hearing body).*

v. Previously acquired ITP data may also be re-evaluated for the presence of *Prohibited Substances* or their *Metabolite(s)* or *Marker(s)* of *Prohibited Substances* or *Prohibited Methods*, at the initiative of the TA, the RMA, *WADA* or the Laboratory at its own discretion. The results of such re-evaluation, if suspicious, shall be communicated to the TA, the RMA or *WADA*, as applicable, and may lead to Further Analysis.

b) Analytical *Testing* Procedures for Further Analysis of Stored *Samples*

i. Further Analysis of stored *Samples* shall be performed in compliance with the ISL, *TD*s, *TL*s and LGs in effect at the time the Further Analysis is performed.

ii. Further Analysis of stored *Samples* includes, notably, but without limitation, the application of newly developed or improved 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*.

iii. 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).

c) Further Analysis of Stored *Samples* Process

i. Use of the "A" *Sample*

- The TA or *WADA* may instruct the Laboratory to use the "A" *Sample* for:
  - Both the ITPs and the "A" CPs; or
  - Only for the ITPs; or
  - Not to use the "A" *Sample* for Further Analysis at all.
- If the Laboratory has been instructed to perform only ITPs on the "A" *Sample*, any suspicious analytical result obtained from the "A" *Sample* shall be considered as a PAAF, irrespective of the Analytical *Testing* Procedure applied, and shall be confirmed using the split "B" *Sample* (see below).
- When a CP is performed on the "A" *Sample* and an *AAF* is reported on this basis, the "B" CP shall be applicable (as per Article 5.3.4.2.2.3).

ii. Use of the split "B" *Sample*

- When the "A" *Sample* is used only for the ITPs or is not used at all during Further Analysis, the "B" *Sample* shall be split and used for analysis.
- The "B" *Sample* shall be split into two fractions, in accordance with Article 5.3.2.2.
- The *Athlete* and/or a representative of the *Athlete* should be invited to witness the splitting procedure. At a minimum, the splitting process shall be conducted in the presence of an appointed Independent Witness.
- Even if present during the splitting procedure, the *Athlete* and/or his/her representative has no right to attend the Analytical *Testing* Procedures to be performed on the first split fraction of the "B" *Sample*, which shall be deemed as the "A" *Sample*.

- In the event an *AAF* is notified based on the results of a CP of the first fraction of the "B" *Sample*, the second split fraction of the "B" *Sample* shall be deemed as the "B" *Sample*. If applicable, a "B" confirmation shall be decided and performed in accordance with Article 5.3.4.2.2.3.

*[Comment to Article 5.3.4.3: 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 ITPs and "A" CPs or "A" CPs only (if the ITPs was/were already performed using the "A" Sample).]*

#### 5.3.4.4 Alternative Biological Matrices

Any negative Analytical *Testing* results obtained from hair, nails, oral fluid, or other biological material shall not be used to counter *AAFs* or *ATFs* from urine or blood (including whole blood, plasma, serum or DBS).

### 5.3.5 Assuring the Validity of Analytical Results

a) The Laboratory shall monitor its analytical performance and the validity of test results by operating quality control schemes, which are appropriate to the type and frequency of Analytical *Testing* performed by the Laboratory.

i. The QC schemes shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.

ii. All quality control procedures shall be documented in the Laboratory Management System.

b) The range of quality control activities include, but are not limited to:

i. Use and monitoring of appropriate QC samples.

- Appropriate positive and negative QCs, prepared in the matrix of analysis, shall be included, and analyzed in every ITPs and CPs [11].
- Appropriate internal standard(s) shall be used for chromatographic methods.
- QC-charts with appropriate warning and action limits shall be regularly used to monitor method performance and inter-batch variability (when applicable) for quantitative determinations (*e.g.*, CPs for Threshold Substances, steroid profile and *ABP* Endocrine Module *Marker* measurements, GC/C/IRMS analyses).

ii. Implementation of an Internal *Quality Assurance* Scheme (iQAS)

- The Laboratory shall establish a functional and robust risk assessment-based iQAS program, which challenges the entire scope of the Analytical

[11] Unless otherwise specified in a *TD*, *TL* or LGs.

*Testing* process (i.e., from *Sample* accessioning through results evaluation).

- The Laboratory shall implement a procedure that prevents the submission of iQAS results into *ADAMS*.
- The iQAS plan shall include and evaluate as many Laboratory procedures as possible, including:
  - The submission of a sufficient number of iQAS test samples on a regular basis (e.g., monthly); and
  - Shall incorporate as many categories of *Prohibited Substances* and *Prohibited Methods* as possible.
- The Laboratory shall have a dedicated Management System document for the iQAS program, which incorporates detailed descriptions for:
  - The planning, preparation, introduction (blind and/or double-blind) of the iQAS samples; and
  - The management of the iQAS results (reviewing and follow-up of nonconformities).

iii. Mandatory participation in the *WADA* EQAS (see *TD* EQAS).

iv. Implementation of Internal Audits

- Internal audits shall be conducted in accordance with the requirements of ISO/IEC 17025 (or ISO 15189, as applicable for *ABP* Laboratories) and shall have a dedicated Management System document incorporating a detailed procedure for:
  - The planning and performance of the audits;
  - The training, selection and authorization of auditors including the specification of their auditing activities; and
  - The management of the internal audit conclusions (reviewing and follow-up of nonconformities).
- For the conduct of internal audits, Laboratories may have their procedures and systems audited by:
  - External auditors selected by the Laboratory (e.g., other Laboratory Directors or other external personnel performing the audit at the request of the Laboratory);
  - Qualified Laboratory staff members, provided that they do not audit their own area of operations;
  - Qualified members of the Laboratory's host organization (e.g., university, institute, company).

### 5.3.6 *Results Management*

#### 5.3.6.1 Review of Results

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

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

c) Requests for Second Opinions

The Laboratory may request a second opinion from other Laboratory Experts (for example, Experts from *WADA* Technical Working Groups) before reporting an *AAF* or *ATF*.

i. Such requests for second opinions may be required by specific *TD*s, *TL*s or LGs, required by *WADA* from certain Laboratory(-ies) for all or for specific Analytical *Testing* Procedures under certain conditions (e.g., following the recent obtaining of *WADA* accreditation or after a period of Suspension or ATR), or requested at the discretion of the Laboratory (e.g., for first detection of novel Analytes or for findings which are difficult to interpret).

ii. Requests for second opinions are not permitted for analytical results associated with the blind or educational EQAS, unless approved or instructed by *WADA*.

iii. When the second provider is not a member of the relevant *WADA* Technical Working Group, they shall be at least a Certifying Scientist for the Analytical *Testing* Procedure and shall be approved to provide second opinions by the Laboratory Director.

iv. The request for second opinions shall be made in writing and the second opinion(s) received shall be recorded as part of the *Sample*'s documentation.

v. 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.

vi. The Laboratory that performed the analysis is responsible for the result and for issuing the final Test Report [12].

[12] Unless otherwise specified in a *TD*, *TL* or LGs.

d) Laboratory Review of *AAFs* and *ATFs*

At a minimum, the review of *AAFs* and *ATFs* shall include:

i. Documentation linking the *Sample* external code (as specified in the DCF) to the Laboratory internal *Sample* code.

ii. LCOC documentation.

iii. ITPs and CPs Analytical Data and calculations.

iv. QC data.

v. Completeness of technical and analytical documentation supporting the reported findings.

vi. Compliance of test data with the Analytical *Testing* Procedure's validation results (e.g., MU).

vii. Assessment of the existence of significant data or information that would cast doubt on or refute the Laboratory findings.

*[Comment to Article 5.3.6.1 d): 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.]*

viii. When the CP result(s) are rejected as *AAF* or *ATF* based on the results review, the reason(s) for the rejection shall be recorded.

### 5.3.6.2 Traceability of Results and Documentation

The Laboratory shall have documented procedures to ensure that it maintains a record related to each *Sample* analyzed.

a) Each step of the Analytical *Testing* shall be traceable to the staff member who performed that step;

b) Critical consumables (*e.g.*, reagents, RMs) used in the relevant steps of the Analytical *Testing* shall be recorded for traceability;

c) Significant deviation from a written Management System procedure shall be recorded;

d) Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record;

e) Requests for information by the TA, RMA or *WADA* to a Laboratory shall be made in writing;

f) LDOCs and CoAs shall be in compliance with the *TD* LDOC.

i. In the case of an *AAF* or *ATF*, the record shall include the data necessary to support the conclusions reported as set forth in and limited by the *TD* LDOC.

ii. Laboratories are not required to produce an LDOC for a Negative Finding, unless requested by a hearing body or disciplinary panel as part of a *Results Management* process or Laboratory disciplinary proceedings.

#### 5.3.6.3 Confidentiality of the Analytical Data and *Athlete's* Identity

a) Confidentiality of the Analytical Data and *Athlete*'s identity shall be observed by all parties (*e.g*., Laboratory, TA, RMA, *WADA,* other parties informed including, where different, National Federations, International Federations, *NOC*s).

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

c) 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.

d) Encrypted emails or documents shall be used for reporting or discussion of *AAFs* or *ATFs* if the *Athlete* can be identified or if any information regarding the identity of the *Athlete* is included.

e) Whenever the Laboratory handles Analytical Data or information where an *Athlete* is identified or identifiable, the Laboratory shall treat such data in accordance with the requirements of the *International Standard* for Data Protection (ISDP).

#### 5.3.6.4 Reporting Test Results

a) A Laboratory shall not conduct any additional Analytical *Testing* on a *Sample* for which the *Athlete* has been charged with a *Code* Article 2.1 anti-doping rule violation unless the case has been finally resolved (as communicated to the Laboratory by the responsible RMA) or consent from the *Athlete* or approval from a hearing body is obtained by the TA (or RMA, if different) – see also Article 5.3.4.3.

b) Unless specifically requested to make a partial submission of test results by the TA (or RMA, if different) or *WADA*, a Laboratory shall not report analytical results for any *Sample* until all analyses detailed in the Analytical *Testing* menu of the relevant DCF have been completed. Therefore:

i. If a Laboratory is requested to report an *AAF*(*s*) for a *Sample*(*s*) before all analyses on that *Sample* have been completed, then the Laboratory shall advise the TA (or RMA, if different) that the *Sample* analysis has not been completed and, in addition, that if the *Athlete* is charged with a *Code* Article 2.1 anti-doping rule violation before

the additional analyses on the *Sample* have been completed, then the additional analyses cannot be conducted until the case has been finally resolved or consent from the *Athlete* or approval from a hearing body is obtained.

ii. If the Laboratory receives a request to conduct additional analyses (e.g., CPs for an atypical or suspicious steroid profile, EPO analysis for a suspicious haematological profile), which are triggered by *ADAMS* notifications or APMU requests after the "A" *Sample* has already been reported as an *AAF*, then the Laboratory shall advise the TA (or RMA, if different) that if the *Athlete* has been charged with a *Code* Article 2.1 anti-doping rule violation, the additional analyses cannot be performed until the case is finally resolved or consent from the *Athlete* or approval from a hearing body is obtained.

c) Reporting Timelines

i. Reporting of "A" *Sample* results should occur in *ADAMS* within twenty (20) days of receipt of the *Sample*.

- The reporting time required for specific occasions (e.g., in preparation for or during Major *Events*) may be substantially less than twenty (20) days, and this should be accorded with the responsible TA(-ies). In such cases, Laboratories may have to prioritize the analysis of Major *Event Samples* over other *Samples*.
- The Laboratory shall inform the TA in writing of any delay in the reporting of "A" *Sample* results, including the applicable reasons.

ii. The LDOCs and/or CoAs should be provided by the Laboratory, only to the relevant RMA or *WADA,* upon request and should be provided within fifteen (15) days of the request, unless a different deadline is agreed upon with the RMA or *WADA*, respectively.

#### 5.3.6.4.1 Reporting Requirements

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

*[Comment to Article 5.3.6.4.1 a): Test results for samples from non-Signatories, except WADA, shall not be reported in ADAMS].*

b) When reporting test results in *ADAMS*, the Laboratory shall include, in addition to the mandatory information stipulated in *ADAMS*, in the relevant *TDs, TL*s or LGs, and in the ISO/IEC 17025 standard, the following:

i. The specific gravity (SG) of the *Sample* (ITP and "A" and "B" CPs).

ii. The name of the RMA, if provided.

iii. Relevant comments, if necessary, for proper interpretation of the test result or recommendations to the TA (for example, for *Target Testing* of the *Athlete*).

*[Comment to Article 5.3.6.4.1 b): The Laboratory shall have a policy regarding the provision of opinions and interpretation of data. An opinion or interpretation may be included in the ADAMS Test Report provided that the opinion or interpretation is clearly identified as such. The basis upon which the opinion has been made shall be documented. An opinion or interpretation may include, but not be limited to, recommendations on how to use results, information related to the pharmacology, metabolism, and pharmacokinetics of a substance, whether the observed results may suggest the need for additional investigations regarding potential environmental contamination causes and/or Further Analysis and whether an observed result is consistent with a set of reported conditions.]*

iv. Specific tests performed, in addition to the Laboratory routine Analytical *Testing* menu (e.g., ERAs, GC/C/IRMS, hGH, blood transfusions, DNA, genomic profiling, etc.).

v. Any irregularities noted on *Samples*.

vi. Any refusal by the *Athlete* and/or his/her representative(s) or the Independent Witness, as applicable, to sign the Laboratory documentation for the "B" *Sample* opening, aliquoting or re-sealing procedures (see Article 5.3.4.2.2.3).

c) The Laboratory is not required to provide any additional Test Report, either in hard-copy or digital format, other than the submission of test results in *ADAMS*. All *ADO*s shall access the Test Reports of their *Samples* in *ADAMS*.

d) Upon request by *WADA*, the Laboratory shall report a summary of the results of analyses performed in a format specified by *WADA*. In addition, the Laboratory shall also provide any information requested by *WADA* in relation to the Monitoring Program (*Code* Article 4.5).

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

i. *AAF*; or

ii. *ATF*; or

iii. Negative Finding; or

*[Comment 1 to Article 5.3.6.4.1 e): In cases when the TA confirms to the Laboratory the existence of an approved TUE for the Prohibited Substance, which is consistent with the PAAF results obtained in the ITP (see Art 5.3.4.2.2.2 c), the Laboratory shall report the result as a Negative Finding as instructed by the TA.]*

iv. Not Analyzed

*[Comment 2 to Article 5.3.6.4.1 e): Any Sample received at the Laboratory and not subject to Analytical Testing for a valid, documented reason (as instructed by or agreed with the TA) such as Sample irregularities, intermediate Samples of a Sample Collection Session, etc. (see Article 5.3.2).]*

#### 5.3.6.4.1.1 Test Report for Non-Threshold Substances

a) "A" *Sample* Test Report

i. Non-Threshold Substances not subject to an *MRL*

- The Laboratory shall report the *Prohibited Substance* or *Prohibited Method* present (i.e., identified) in the "A" *Sample* (in accordance with the identification and reporting requirements established in the *TD* IDCR, *TD* MRPL, or other applicable *TD*s, *TL*s or LGs);

  *[Comment to Article 5.3.6.4.1.1 a): 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.]*

- The Laboratory is not required to report concentrations for Non-Threshold Substances that are not subject to an *MRL*. However, the Laboratory should provide estimated concentrations, when possible and upon request by the TA, RMA 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 specifying that the concentration was estimated by an Analytical *Testing* Procedure that has not been validated for quantitative purposes.

ii. Non-Threshold Substances subject to an *MRL*

- The Laboratory shall report the *Prohibited* Substance when the relevant target Analyte(s) [13] identified in the "A" *Sample* (in accordance with the *TD* IDCR) are present at

[13] The relevant target Analytes of a Non-Threshold Substance subject to an *MRL* are those Analyte(s) to which the *MRL* is applied (i.e., the *Prohibited Substance* and/or its *Metabolite*(s) and/or its *Marker*(s), as defined in the *TD* MRPL).

an estimated concentration which is higher than the corresponding *MRL* (see *TD* MRPL);

- The Laboratory shall report the estimated concentrations for Non-Threshold Substances subject to an *MRL* upon request by the TA, RMA or *WADA*. However, the Laboratory shall specify that the concentration was estimated by an Analytical *Testing* Procedure that has not been validated for quantitative purposes.

b) "B" *Sample* Test Report

For Non-Threshold Substances, irrespective of whether they are subject to an *MRL*, the Laboratory Test Report for the "B" *Sample* shall only specify the *Prohibited Substance* or *Prohibited Method* present (i.e.*,* identified), at any level, in the "B" *Sample* (in accordance with the identification requirements established in the *TD* IDCR, *TD* MRPL, or other applicable *TD*s, *TL*s or LGs). The Laboratory is not required to estimate nor report the concentration of the Non-Threshold Substance in the "B" *Sample*.

#### 5.3.6.4.1.2 Test Report for Threshold Substances

a) "A" *Sample* Test Report

i. For Threshold Substances, the Laboratory Test Report for the "A" *Sample* shall establish that the identified *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* is present at a level of measured analytical values (e.g.*,* concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) greater than the *DL* (see *TD DL*), and/or that the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* is of exogenous origin.

ii. In the event that the Threshold Substance, identified as such in the *Prohibited List* and the *TD DL*, is detected in the presence of a diuretic or masking agent, the Laboratory shall establish the presence (i.e., the identity) of the *Prohibited Substance* and/or its *Metabolite(s)* and/or or its *Marker(s)* (in accordance with the *TD* IDCR or other applicable *TD*s, *TL*s or

LGs) and report it as an *AAF*, in addition to the reporting of the diuretic(s) or masking agent(s). In such cases, the Laboratory is not required to report the estimated concentration of the Threshold Substance.

b) "B" Sample Test Report

i. Exogenous Threshold Substances

The Laboratory Test Report for the "B" *Sample* shall only establish the presence (i.e., the identity) of the *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* (in accordance with the *TD* IDCR or other applicable *TD*s, *TL*s or LGs). The Laboratory is not required to estimate/quantify nor report the concentration(s) of the Threshold Substance.

ii. Endogenous Threshold Substances

- The Laboratory Test Report for the "B" *Sample* shall establish that:
  - The identified (in accordance with the *TD* IDCR or other applicable *TD*s, *TL*s or LGs) *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* is present at a level of measured analytical values (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*), which is greater than the *DL* [14], or
  - The *Prohibited Substance* or its *Metabolite(s)* or *Marker(s)* is of exogenous origin.
- In the event that the Threshold Substance, identified as such in the *Prohibited List* and the *TD DL*, is detected in the presence of a diuretic or masking agent, the Laboratory shall establish the presence (i.e., the identity) of the *Prohibited Substance* and/or its *Metabolite(s)* and/or or its *Marker(s)* (in accordance with the *TD* IDCR or other applicable *TD*s, *TL*s or LGs) and report it as

[14] The Thresholds for endogenous Threshold Substances have been established based on reference population statistics and already incorporate a guard band that reflects the uncertainty of the measurements. Therefore, the Threshold constitutes the *DL*. The assay MU shall not be added to the test result for reporting an *AAF* or an *ATF*.

an *AAF*, in addition to the reporting of the diuretic(s) or masking agent(s). In such cases, the Laboratory is not required to estimate nor report the concentration of the Threshold Substance in the B" *Sample*.

### 5.3.7 Storage of *Samples* [15]

a) The Laboratory shall store *Samples* in a restricted and secure location under appropriate storage conditions and continuous chain of custody.

b) The Laboratory shall maintain all chain of custody and other records (either as hard-copy or in digital format) pertaining to stored *Samples.*

c) *Samples* shall be stored for the applicable minimum storage periods defined in Table 1 below after reporting all *Sample* results ("A" and "B", if applicable) in *ADAMS* and may be stored for a maximum of ten (10) years after the *Sample* collection date, unless *Sample* direct identifiers are removed for secondary use of the *Sample*(s) (see Article 5.3.8.2).

d) *Samples* shall be stored for longer than the minimum storage periods defined in Table 1 below if requested by the TA (or RMA, if different) or *WADA*.

e) If the Laboratory has been informed by the TA (or RMA, if different) or *WADA* (in writing and within the applicable minimum storage period as defined in Table 1) that the analysis of a *Sample* is challenged, disputed or under investigation, the Laboratory shall retain both the "A" and "B" *Samples* until further notice by the TA (or RMA, if different) or *WADA*, as applicable

**Table 1. Minimum *Sample* Storage Periods**

<table>
<tr><th colspan="2" rowspan="2">Sample Matrix</th><th rowspan="2">Storage conditions</th><th colspan="3">Minimum Storage times [1]</th></tr>
<tr><th>Negative Finding</th><th>Not Analyzed</th><th>AAF / ATF [2, 3]</th></tr>
<tr><td colspan="2">Urine</td><td>Frozen (-15°C or less)</td><td>6 months</td><td>3 months</td><td>6 months</td></tr>
<tr><td rowspan="3">Venous Blood</td><td>Whole Blood</td><td>Refrigerated</td><td>1 month</td><td>1 month</td><td>3 months</td></tr>
<tr><td>Plasma [5]</td><td rowspan="2">Frozen<br>• -15°C or less up to 3 months<br>• -70°C or less for more than 3 months</td><td rowspan="3">3 months</td><td rowspan="3">3 months</td><td rowspan="3">6 months</td></tr>
<tr><td>Serum [5]</td></tr>
<tr><td>Capillary Blood</td><td>DBS [4]</td><td>Frozen<br>• -15°C or less</td></tr>
</table>

[1] The Laboratory may charge storage costs to the TA (or RMA, if different) or *WADA*, as applicable, for the storage of *Samples* for periods longer than the stated minimum storage times. However, the Laboratory may store *Samples* beyond the applicable

[15] This refers to "A" and "B" *Samples* and *ABP* Blood *Samples* stored in *Sample* collection containers (urine collection bottles, blood collection tubes, DBS devices) and should not be confused with access to Aliquots, which should be accessible to analysts for the performance of Analytical *Testing* Procedures. However, minimum and maximum retention times apply to any Aliquot(s) of a *Sample* that remains after completion of the Analytical *Testing*.

minimum storage times at their own discretion and expense. In such cases, the Laboratory shall inform the responsible TA. Any Further Analysis on these *Samples* will require the approval of the TA or *WADA*.

[2] If the "B" *Sample* CP is not performed, the Laboratory may dispose of both the "A" and "B" *Samples* after the corresponding minimum storage time following the reporting of the "A*" Sample* analytical result. However, if the "B" *Sample* CP is performed, then the Laboratory shall retain both the "A" and "B" *Sample(s)* for the corresponding minimum storage time after reporting the "B" *Sample* analytical result.

[3] Nevertheless, the Laboratory shall contact and inform the relevant TA and *WADA* before disposing of any *Samples* with *AAF* for which the TA (or RMA, if different) has not provided instructions regarding whether to perform the "B" CP (see Article 5.3.4.2.2.3).

[4] If the Analytical *Testing* has been performed on the cellular fraction of a DBS *Sample*, then the minimum storage periods established for whole (venous) blood *Samples* shall be followed.

[5] Following the conclusion by the Laboratory of a PAAF in a plasma or serum "A" *Sample*, the Laboratory shall transfer the corresponding "B" *Sample* tube to freezing at -70 °C or less. After the "B" *Samples* is opened for CP aliquoting, the re-sealed "B" *Sample* shall be returned to storage at -70°C or less.

#### 5.3.7.1 Long-term Storage of *Samples*

At the direction of the TA or *WADA*, or at the Laboratory's own decision and expense (in which case the Laboratory shall inform the TA) any urine or serum/plasma/DBS *Sample* may be stored in long-term storage (i.e., beyond the minimum storage periods established in Article 5.3.7) for up to ten (10) years after the *Sample* collection date for the purpose of Further Analysis (see Article 5.3.4.3).

*Sample*(s) may be stored in long-term storage under the custody of a Laboratory or transferred to another Fit-for-Purpose facility. The TA shall retain the *Sample* collection records pertaining to all stored *Samples* for the duration of *Sample* storage.

a) Laboratories as *Sample* Custodians

i. The Laboratory shall ensure that *Samples* are stored according to established protocols in a secure location in the Laboratory's permanent controlled zone and under continuous chain of custody.

ii. The written request from the TA or *WADA* for long-term storage of *Samples* shall be properly documented.

iii. *Samples* may also be transported for long-term storage to a specialized, secure *Sample* storage facility, which is located outside the Laboratory's permanent controlled zone and is under the responsibility of the Laboratory or may be transported to another Laboratory.

- If the external *Sample* storage facility is not covered by the Laboratory's ISO/IEC 17025 accreditation (or ISO 15189, as applicable for *ABP* Laboratories), then the subcontracted external storage facility shall be Fit-for Purpose and have its own ISO accreditation or certification (e.g., 17025, 20387, 9001);
- The transfer of the *Samples* to the external long-term storage facility or Laboratory shall be recorded;
- If *Sample(s)* are to be transported for storage at a location outside the secured area of the Laboratory that first analyzed

the *Sample(s),* the Laboratory shall secure the "A" *Sample(s)* to be shipped either by re-sealing individual "A" *Sample* container(s) with a tamper-evident sealing system, which has similar capabilities for security and integrity as the original sealing system, or by sealing the box in which the *Sample(s)* are shipped in a manner that maintains *Sample* integrity and chain of custody. Neither the *Athlete* nor his or her representative nor an Independent Witness is required to be present for this procedure;

*[Comment to Article 5.3.7.1 a): For example, Sample(s) may be resealed with new resealing systems (e.g., new bottlecaps) produced by the manufacturer of an appropriate Sample collection equipment that replicates the security and tamper-evident functionality of the original seal. The resealing system of shipped "A" Sample(s) shall be tamper evident.]*

- "B" *Sample(s)* to be shipped shall be individually sealed, either in the original, sealed "B" *Sample* container(s) or, if previously opened, by re-sealing the individual "B" *Sample* container(s) with a tamper-evident sealing system, which has similar capabilities for security and integrity as the original sealing system. The resealing of the "B" *Sample(s),* if necessary, shall be witnessed by either the *Athlete* or his/her representative or by an appointed Independent Witness;
- During transport and long-term storage, *Sample(s)* shall be stored at a temperature appropriate to maintain the integrity of the *Sample(s).* In any anti-doping rule violation case*,* the issue of the *Sample*'s transportation or storage temperature shall be considered where failure to maintain an appropriate temperature could have caused the *AAF* or other result upon which the anti-doping rule violation is based.

iv. The Laboratory shall retain all LCOC and technical records (as per ISO/IEC 17025) pertaining to a stored *Sample* for the duration of *Sample* storage, either as hard-copy or in digital format. In addition, the Laboratory may retain *Sample* Analytical Data which would allow retrospective analysis of such data, for example, for the purpose of identifying signals for novel *Metabolite(s)* of *Prohibited Substance(s)* or *Marker(s)* of *Prohibited Substance(s)* or *Prohibited Method(s)* (e.g.*,* full-scan mass spectrometry data) as detailed in Article 5.3.4.3.

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

b) TA as *Sample* Custodian

*Sample(s)* may also be transported for long-term storage to a Fit-for-Purpose, secure *Sample* storage facility, which is under the responsibility of the TA that has ownership over the *Samples*.

i. The external storage facility shall have its own ISO accreditation or certification (e.g., 17025, 20387, 9001) and shall maintain security requirements comparable to those applicable to a Laboratory.

- The TA shall ensure that *Samples* are stored according to established protocols in a secure location under continuous chain of custody;
- The TA's written request to the Laboratory for the transfer of the *Sample(s)* to long-term storage shall be properly documented;
- The transfer of the *Samples* to the external long-term storage facility shall also be recorded;
- The Laboratory shall secure the *Sample(s)* for transportation to the long-term storage facility as described above.

ii. The Laboratory shall retain all LCOC and technical records (as per ISO/IEC 17025) pertaining to all *Samples* transferred for long-term storage for the duration of *Sample* storage, either as hard-copy or in digital format. In addition, the Laboratory may retain *Sample* Analytical Data which would allow retrospective analysis of such data.

iii. The Laboratory shall transfer the *Sample*'s external chain of custody and other non-analytical records to the TA, either as originals or copies, immediately or upon request.

### 5.3.8 Secondary Use or Disposal of *Samples* and Aliquots

The Laboratory shall maintain Management System procedure(s) pertaining to the secondary use of *Samples* or Aliquots for research or *Quality Assurance*, as well as for the disposal of *Samples* and Aliquots.

The requirements of this Article 5.3.8 apply *mutatis mutandis* to an *ADO* that takes custody of *Samples* for long-term storage.

When the minimum applicable *Sample* storage period has expired (see Table 1 in Article 5.3.7), and neither the TA nor *WADA* have requested the long-term storage of the *Sample* for the purpose of Further Analysis or have informed the Laboratory that a challenge, dispute, or longitudinal study is pending, or if the Laboratory has not made its own decision to keep the *Samples* for long-term storage, the Laboratory shall do one of the following with the *Sample(s)* and Aliquots as soon as practicable:

#### 5.3.8.1 Disposal of the *Sample(s)* and Aliquots

The disposal of *Samples* and Aliquots shall be recorded under the LCOC.

### 5.3.8.2 Secondary use of *Samples* and Aliquots for Research and *Quality Assurance* Purposes

a) Before analyzing *Samples* and/or assessing Analytical Data for research or *Quality Assurance*, direct identifiers shall be removed or irreversibly altered as to prevent *Samples* and Analytical Data from being traced back to a particular *Person* (see *Code* Article 6.3).

b) Only after the removal or irreversible change of identifiers, may a *Sample* or Aliquot be used for:

   i. Research, only if the *Athlete's* has consented to the use of their *Sample* for research; or

      *[Comment to Article 5.3.8.2 b): Athlete consent for research, as declared in the DCF or as obtained by other means, shall be recorded in the Laboratory's documentation for reference.]*

   ii. *Quality Assurance*, for which *Athlete*'s consent is not required (see also Comment to *Code* Article 6.3).

c) The use of *Samples* and Aliquots for the purposes of this Article 5.3.8.2 is subject to the following conditions:

   i. The Laboratory shall respect *Code* Articles 6.3 and 19, and the ISL Code of Ethics requirements related to research, types of permitted research, and respect of ethical standards for research or *Quality Assurance* studies involving human subjects.

   ii. The Laboratory shall not make any attempt to re-identify an *Athlete* from *Samples* or Aliquots used for the purposes of this Article 5.3.8.2 or data arising from any research or *Quality Assurance* analysis.

   iii. The Laboratory shall consult the applicable *WADA* guidelines, national regulations, guidance, or authorities to determine whether a study should be considered as falling under research or *Quality Assurance*.

      *[Comment to Article 5.3.8.2 c): If the Laboratory is unsure whether a study can proceed without Athlete consent after consulting the foregoing sources, the Laboratory shall consult with WADA].*

d) In the event the Laboratory wishes to transfer *Sample(s)* or Aliquots to be used for the purposes of this Article 5.3.8.2 to another Laboratory or a third-party research institution or group, or wishes to partner with another Laboratory or research institution or group for the purpose of an Article 5.3.8.2 study, the Laboratory shall subject the receiving party to the conditions described in this Article 5.3.8.2 by way of a written agreement and shall prohibit the receiving party from further transferring any *Sample(s)* or Aliquots or related data to another party.

### 5.3.9 Control of Nonconformities in Analytical *Testing*

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

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

b) Risk Minimization:

   i. Laboratories shall take corrective actions in accordance with ISO/IEC 17025.

   ii. When conducting a corrective action investigation, the Laboratory shall perform and record a thorough RCA of the nonconformity.

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

### 5.3.10 Complaints

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

## 5.4 Management Requirements

### 5.4.1 Organization

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

### 5.4.2 Management Reviews

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

### 5.4.3 Document Control

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

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

b) The Laboratory shall implement a procedure in its Management System to ensure that the contents of ISL, *TD*s, *TL*s and LGs are incorporated into the Laboratory's SOPs by the applicable effective date and that implementation is completed, recorded, and assessed for compliance.

   i. If this is not possible, the Laboratory shall send a written request for an extension beyond the applicable effective date for consideration by *WADA*.

ii. 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 or approval status.

### 5.4.4 Control and Storage of Technical Records

a) The Laboratory shall keep a copy of all *Sample* records to the extent needed to produce LDOCs or CoAs, in accordance with the *TD* LDOC, in a secure storage until *Sample* disposal or anonymization (see Article 5.3.8).

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

### 5.4.5 Cooperation with Customers and with *WADA*

Cooperation with customers shall be handled in accordance with ISO/IEC 17025 (or ISO 15189, for *ABP* Laboratories).

a) Ensuring Responsiveness to *WADA*

The Laboratory Director or his/her designee shall:

i. Ensure adequate communication with *WADA* in a timely manner.

ii. Provide complete, appropriate, and timely explanatory information as requested by *WADA*.

iii. Report to *WADA* any unusual circumstances or information regarding Analytical *Testing,* patterns of irregularities in *Samples*, or potential *Use* of new substances.

iv. Provide documentation to *WADA* (e.g.*,* Management System documentation, SOPs, contracts (not including commercial or financial information) with *Signatories*, or with SCAs or *DTP*s working on behalf of *Signatories*) upon request to ensure conformity with the rules established under the *Code* as part of the maintenance of *WADA* accreditation. This information shall be treated in a confidential manner.

b) Ensuring Responsiveness to TA and/or RMA

i. The Laboratory Director shall be familiar with the TA rules and the *Prohibited List.*

ii. The Laboratory Director shall interact with the TA and/or RMA regarding 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 TA and/or RMA 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 TA and/or RMA when requested or when there is a potential for misunderstanding of any aspect of the Analytical *Testing* process, Laboratory Test Report, CoA or LDOC;
- If requested by the TA and/or RMA, the Laboratory shall provide advice and/or opinion to the TA and/or RMA regarding the *Prohibited Substances* and *Prohibited Methods* included in the Analytical *Testing* Procedures.

c) Provide evidence and/or expert testimony on any test result or report produced by the Laboratory as required in administrative, arbitration, or legal proceedings.

i. The requests from such expert testimonies shall originate, in writing, from the TA, RMA, *WADA* or hearing bodies as part of the *Results Management* process.

ii. The Laboratory shall not provide expert testimony to *Athletes* or *Athletes*' representatives, including their legal counsels.

d) Responding to any complaint submitted by a TA or RMA concerning the Laboratory and its operation.

i. As required by ISO/IEC 17025, the Laboratory shall actively monitor the quality of the services provided to the relevant *ADO*s, including the introduction of an annual questionnaire to clients to assess their satisfaction (or otherwise) with the performance of the Laboratory.

ii. There should be documentation that the TA or RMA concerns have been incorporated into the Laboratory's Management System where appropriate.

## 6.0 *WADA* Laboratory and *ABP* Laboratory Monitoring and Performance Evaluation Activities

*WADA* shall monitor Laboratory accreditation or *ABP* Laboratory approval status by reviewing their compliance with the applicable requirements listed in the ISL and related *TD*s, *TL*s and LGs, as well as by monitoring their performance in the EQAS and during routine Analytical *Testing*.

### 6.1 *WADA* Laboratory and *ABP* Laboratory Monitoring

*WADA* shall monitor the compliance and performance of Laboratories and *ABP* Laboratories through a series of monitoring and assessment activities, which include but are not limited to:

a) The *WADA* EQAS Program.

b) Laboratory and *ABP* Laboratory Assessments.

c) Removal of *Samples* for analysis, Further Analysis or Quality Assessment purposes.

#### 6.1.1 *WADA* EQAS

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 normative standards (e.g., ISL, *TD*s, *TL*s and LGs), 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 Laboratory Analytical *Testing* Procedures. *WADA* is committed to conduct its EQAS to the highest standard and to ensure that it meets the goals and needs of its stakeholders, including the EQAS Participants, in accordance with the requirements of the ISO/IEC 17043 standard (Conformity Assessment - General Requirements for the Competence of Proficiency Testing Providers).

*WADA* regularly distributes through its subcontracted EQAS sample provider(s) urine or blood EQAS samples (including blind, double-blind and educational EQAS samples) to Laboratories and, when applicable, to probationary laboratories to continually monitor their capabilities, to evaluate their proficiency, and to improve test result uniformity between Laboratories. In addition, *WADA* distributes EQAS samples to Candidate Laboratories and Probationary laboratories as part of Pre-Probationary Tests (PPT) and Final Accreditation Tests (FAT), respectively (see Articles 4.1.2.6 and 4.1.3.10).

As part of its Laboratory monitoring activities, and with the main purpose of assisting Laboratories in their continuous improvement of performance, *WADA* may distribute additional EQAS *Samples* to Laboratories according, but not limited to, the following criteria (or other valid reasons, as determined by *WADA*):

a) To monitor the effectiveness of corrective action implementation after questionable or unsatisfactory performance in *WADA* EQAS or in routine Analytical *Testing*.

b) As part of *WADA* Laboratory assessments (see Article 6.1.2).

c) During Major *Events* (see Article 4.3.1.2).

d) When substantiated intelligence information is received by *WADA* indicating questionable or unsatisfactory Laboratory performance.

e) To assess Laboratory competence in applying a specific Analytical *Testing* Procedure, which is not part of the Laboratory's routine Analytical *Testing* menu, when there are an insufficient number of *Samples* received for analysis.

Laboratories and *ABP* Laboratories also participate in the EQAS for the *ABP* blood analysis on a regular basis (e.g., monthly). *WADA* subcontracts this *ABP* EQAS program to an ISO/IEC 17043-accredited external Proficiency Test Provider.

For full details on the *WADA* EQAS, including types, number, and composition of EQAS samples, as well as Laboratory requirements for the analysis of EQAS samples and reporting of EQAS results, refer to the *TD* EQAS.

### 6.1.2 Laboratory and *ABP* Laboratory Assessments

*WADA* reserves the right to inspect and assess Laboratories or *ABP* Laboratories by conducting document audits and/or on-site and/or remote (on-line) assessments at any time. In addition, *WADA* performs assessments of Candidate Laboratories and Probationary laboratories as part of PPT and FAT, respectively (see Articles 4.1.2.6 and 4.1.3.10).

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

#### 6.1.2.1 Types of Laboratory Assessments

*WADA* Laboratory and *ABP* Laboratory Assessments fall into one of the following two (2) categories:

a) Assessments Related to Laboratory Accreditation or *ABP* Approval Procedures

This type of assessment is conducted in relation (but not limited) to the following Laboratory accreditation or *ABP* approval procedures:

i. PPT of Candidate Laboratories (see Article 4.1.2.6).

ii. FAT of Probationary Laboratories (see Article 4.1.3.10).

iii. Laboratory preparation for Analytical *Testing* during Major *Events* (see Article 4.3.1.1).

iv. Imposition of an (provisional) ATR or (Provisional) Suspension of a Laboratory or (see Articles 7.1.1.3 and 7.2).

v. Suspension of an *ABP* Laboratory (see Article 7.6).

b) Assessments Related to *WADA*'s Regular Laboratory or *ABP* Laboratory Monitoring Activities

As part of *WADA*'s mandate to monitor Laboratory and *ABP* Laboratory performance, *WADA* has implemented a program of regular assessments of accredited and *ABP*-approved laboratories. The assessments are aimed at evaluating Laboratory operations and, when needed, provide guidance to strengthen laboratory performance and ensure compliance with the ISL and related *TD*s*, TL*s and LGs.

Scheduling of Laboratory and *ABP* Laboratory assessments is done in consultation with the *WADA* Lab EAG and shall be guided by the following principles:

i. Prioritization of assessments shall be based on laboratory performance and compliance with *WADA* standards, including (but not limited to):

- EQAS and routine Analytical *Testing* performance;
- Failure to implement mandatory analytical procedures, or issues with Laboratory operational environment (e.g.*,* lack of independence, clients, low number of *Samples* analyzed, insufficient R&D activities);
- Intelligence information received by *WADA* may also trigger a Laboratory assessment.

ii. *WADA*'s objective is to perform an assessment of each Laboratory or *ABP* Laboratory within a reasonable time frame. However, a Laboratory or *ABP* Laboratory may be assessed more or less frequently in consideration of point i. above and as determined by *WADA*.

*WADA* shall inform the Laboratories about which Laboratories were assessed, and the reasons for the assessment, on an annual basis.

#### 6.1.2.2 Assessment Requirements

a) Assessment Team

*WADA* shall appoint an Assessment Team consisting of a Lead Assessor (Team Leader, who shall be a *WADA* staff member) and, where required, a suitable number of Technical Experts for the scope of the assessment.

i. In addition to *WADA* representative(s), the Assessment Team will include members of the Lab EAG and, where appropriate, external Technical Experts (for example, members of *WADA* technical working groups).

ii. The Assessment Team members may include Laboratory Directors or scientists from other Laboratories.

iii. In addition, within the framework of the *WADA*-ILAC cooperation, *WADA* may invite representative(s) of the Accreditation Body, responsible for the Laboratory's or *ABP* Laboratory's ISO/IEC 17025 (or ISO 15189) accreditation, as observers during part(s) or the entire duration of the assessment.

*WADA* shall inform the Laboratory or *ABP* Laboratory, in advance, of the *WADA* Assessment Team composition, as well as the invited Accreditation Body *observers* (if applicable). Thereby, the Laboratory or *ABP* Laboratory will be provided the opportunity to lodge objection(s), if any, to the appointment of any Assessment Team member(s) or Accreditation Body observer(s) with reasonable justification (e.g., perceived conflicts of interest). *WADA* shall consider the objection(s) raised and reserves the right to reject the objection if determined to be unfounded.

b) Assessment Agenda

For an announced assessment, *WADA* shall also provide the Laboratory or *ABP* Laboratory, in advance, a draft Assessment Agenda, as well as requests to provide Laboratory or *ABP* Laboratory documentation (e.g., Laboratory ISO/IEC 17025 accreditation certificate and scope of accreditation, most recent ISO/IEC 17025 assessment report, Laboratory staff list and organizational chart, list of RMs/RCs, Analytical Method Validation Reports and Management System documentation, etc.).

c) Assessment Report

Following the conduct of an assessment, *WADA* shall provide an Assessment Report with the outcomes of the assessment, including any identified nonconformities for the Laboratory or *ABP* Laboratory to implement the necessary improvements. Identified nonconformities shall be addressed by the Laboratory or *ABP* Laboratory and corrective measures reported to *WADA* within thirty (30) days, or as

otherwise indicated by *WADA*. For further evaluation of Laboratory nonconformities, refer to the *TD* PERF.

### 6.1.3 Removal of *Samples* by *WADA*

a) Removal of *Samples* for Analysis or Further Analysis

i. Within the context of an investigation or Laboratory performance monitoring activity (for example, during an on-site *WADA* Laboratory assessment), *WADA*, initially at its expense, may remove *Sample(s)* from a Laboratory (see *Code* Article 6.8) to conduct Further Analysis, or analysis of the *Sample* (if the analytical results for that *Sample* have not yet been reported) for the purpose described in *Code* Article 6.2.

*[Comment to Article 6.1.3a): 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 removal, shipping and analysis or Further Analysis of the Samples from the Laboratory.]*

ii. *WADA*, at its discretion, 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 Laboratory(-ies) selected by *WADA*.

iii. *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).

iv. In connection with its monitoring of Laboratory performance, *WADA* may direct Further Analysis of a *Sample* which has resulted in a *Code* Article 2.1 anti-doping rule violation charge before the case has been finally resolved and without consent of the *Athlete* or approval from a hearing body as established in *Code* Article 6.5, provided that the analytical result from that Further Analysis cannot be used against the *Athlete* (for example, re-analysis of *Samples* which a Laboratory has reported as *AAF*s when the Laboratory has been determined to have reported False *AAF*(s) using the same Analytical Method).

b) Removal of *Samples* for Laboratory Quality Assessment

*WADA* may also direct the re-analysis of de-identified *Samples*, which have met the conditions described in Article 5.3.8.2, for purposes of Laboratory *Quality Assurance* and education, including the implementation of a system of transfer of *Samples* between Laboratories. In this regard, the number of *Samples* directed by *WADA* for re-analysis may vary.

*[Comment to Article 6.1.3b): A transfer of Samples between Laboratories shall apply only to Samples collected by Signatories.]*

### 6.1.4 *WADA* Laboratory Monitoring and Assessment during a Major *Event*

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

*WADA*, in conjunction with the *MEO* or relevant International Federation, may submit double-blind EQAS samples to the Laboratory. The satisfactory analysis of the double-blind EQAS samples is a mandatory requirement for the performance of Analytical *Testing* during a Major *Event* (see Article 4.3.1.2).

## 6.2 Evaluation of Laboratory Nonconformities

The *WADA* system of Laboratory and *ABP* Laboratory EQAS and routine Analytical *Testing* performance evaluation has been developed with the objective of setting a transparent and balanced evaluation of Laboratory, Probationary Laboratory and *ABP* Laboratory operations. It is based on the principle of proportionality and is focused on improving Analytical *Testing* capabilities and, in the case of Probationary Laboratories, their readiness for obtaining *WADA* accreditation. It is ultimately aimed at strengthening, and maintaining confidence in, the anti-doping Laboratory system for the benefit of clean *Athletes*.

Laboratories shall implement remedial actions when any aspect in the conduct of Laboratory activities does not conform with the established procedures and requirements of the ISO/IEC 17025 (or ISO/IEC 15189, if applicable, for an *ABP* Laboratory), the ISL, or its associated *TD*s, *TL*s and LGs.

For full details on the *WADA* Laboratory Performance Evaluation Procedures, including the classification of nonconformities, the process of review of Laboratory corrective action(s) to remedy nonconformities, the evaluation of False *AAFs* and False Negative Findings, and the *WADA* Penalty Point System, refer to the *TD* PERF.

## 7.0 Laboratory and *ABP* Laboratory Disciplinary Procedures

*WADA* shall regularly review the compliance of Laboratories with the mandatory requirements listed in the ISL and related *TD*s and *TL*s. 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.

Compliance with all the requirements established in Article 4.1.4.2, including satisfactory performance by a Laboratory in the EQAS and in routine Analytical *Testing*, as determined by *WADA*, is a critical requirement for the maintenance of the Laboratory's *WADA* accreditation.

### 7.1 Withdrawal of *WADA* Accreditation

A Laboratory's *WADA* accreditation may be suspended or revoked, or subject to an ATR, whenever the Laboratory fails to comply with the ISL and/or *TD*s and/or *TL*s, or where the Suspension, Revocation or ATR is otherwise required in order to protect the World Anti-Doping Program (e.g., integrity of the *Samples*, the Analytical *Testing* process or the interests of the Anti-Doping Community).

#### 7.1.1 ATR or Suspension of *WADA* Accreditation

##### 7.1.1.1 Laboratory Noncompliances Leading to ATR or Suspension of *WADA* Accreditation

Noncompliances with the ISL that may lead to an ATR or Suspension include, but are not limited to:

a) Noncompliance(s) with the ISL Code of Ethics.

b) Suspension, or withdrawal of ISO/IEC 17025 accreditation.

c) Accumulation of the maximum allowed number of penalty points for the EQAS and/or Analytical *Testing*, as determined by the application of the Points Scale Table described in the *TD* on Laboratory Performance Evaluation, *TD* PERF.

d) Reporting of a False *AAF* with *Consequences* for an *Athlete.*

e) Failure to establish and/or maintain administrative and operational independence as described in Article 4.1.4.2.5.

f) Repeated reporting of False *AAFs* and/or False Negative Findings:

*[Comment 1 to Article 7.1.1.1 f): Lab EAG 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 the Laboratory has satisfactorily corrected the noncompliances.]*

i. The reporting of two (2) or more independent False *AAFs* in the EQAS per twelve (12)-month period, or

ii. The reporting of three (3) or more independent *False AAFs*, including EQAS and routine Analytical *Testing*, per twelve (12)-month period, or

iii. The reporting of three (3) or more independent False Negative Findings in the EQAS per twelve (12)-month period, or

iv. The reporting of four (4) or more independent False Negative Findings, including EQAS and routine Analytical *Testing*, per twelve (12)-month period, or

v. Any combination of four (4) or more independent False *AAFs* and False Negative Findings, including EQAS and routine Analytical *Testing*, per twelve (12)-month period.

*[Comment 2 to Article 7.1.1.1 f): Noncompliant analytical findings, as detailed above, are determined to be independent, if produced by different and unrelated root causes (based on a satisfactory RCA investigation), as determined by the Lab EAG.]*

g) Failure to implement a *TD* or *TL* by the effective date without prior approval by *WADA*.

h) Failure to comply with any of the requirements or standards listed in the ISL and/or *TD*s and/or *TL*s.

i) Serious and repeated noncompliances with results reporting timelines (see Article 5.3.6.4).

j) Failure to take appropriate corrective action after an unsatisfactory performance during routine Analytical *Testing* or in a blind EQAS or double-blind EQAS round.

k) Failure to take appropriate corrective action for ISL and/or *TD* and/or *TL* noncompliance(s) identified from *WADA* Laboratory assessment(s).

l) Failure to analyze the minimum number of *Samples* indicated in Article 4.1.4.2.8.

m) Failure to cooperate with *WADA* or the relevant TA or RMA in providing documentation.

n) Laboratory staff and/or management issues, including but not limited to:

i. Major changes in senior Laboratory management positions (e.g., Laboratory Director, Certifying Scientist(s), Quality Manager) without proper and timely notification to *WADA*.

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

iii. Failure to guarantee the competence and/or proper training of scientific staff including, for example, the qualification of analysts as Certifying Scientists (see Article 5.2.2.3).

iv. 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.

o) Failure to implement and document adequate R&D and Sharing of Knowledge activities.

p) Loss of sufficient Laboratory support and resources that affects the quality and/or viability of the Laboratory, as determined by *WADA*.

q) A high number of major noncompliance(s) with the ISL and/or *TD*s and/or *TL*s identified during *WADA* Laboratory assessments which demonstrates an unacceptable risk in the full reliability and accuracy of Analytical *Testing* and the accurate reporting of test results by the Laboratory.

r) Failure to cooperate in a *WADA* enquiry in relation to the activities of the Laboratory.

#### 7.1.1.2 Suspension of Accreditation and ATR

Upon recommendation by the Lab EAG, the Chair of the *WADA* Executive Committee may suspend a Laboratory's *WADA* accreditation or impose an ATR against a Laboratory in cases of major noncompliance(s) with the ISL and/or *TD*s and/or *TL*s based on the Laboratory's performance during the EQAS and/or during routine Analytical *Testing* (see Article 7.1.1.1).

Unless otherwise determined by *WADA*, a Laboratory's *WADA* accreditation shall be subject to a Suspension, and not to an ATR, when the sanction imposed on the Laboratory impacts Analytical Methods or target Analytes that are included in the Laboratory's standard *IC* or *OOC* Analytical *Testing* menus, because it would affect the analysis of all respective urine and/or blood *Samples* received by the Laboratory.

*[Comment 1 to Article 7.1.1.2: If WADA determines that the noncompliance(s) leading to a Suspension or ATR 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.]*

#### 7.1.1.3 Immediate Provisional Suspension or Immediate Provisional ATR

The Lab EAG shall make a recommendation to the Chair of the *WADA* Executive Committee that a Laboratory be subject to an immediate Provisional Suspension or immediate provisional ATR if a Laboratory has reported a False *AAF* with *Consequences* for an *Athlete*.

In such cases, the Laboratory shall immediately cease all affected analytical activities and inform its clients that it has been provisionally suspended or subjected to a provisional ATR. The Laboratory shall implement satisfactory corrective action(s) to resolve the nonconformity within a reasonable period (*i.e*., within ten (10) days during routine Analytical *Testing*, or during Major *Events*, within forty-eight (48) hours of notification of the False *AAF* (see Article 7.7)).

a) If the nonconformity is satisfactorily resolved within the established timeframe, *WADA* nevertheless reserves the right to send extra EQAS samples or perform an assessment of the Laboratory before lifting the Provisional Suspension or provisional ATR, at *WADA*'s discretion, and will use best efforts to notify the Laboratory of such decision in an expedited manner.

b) If the nonconformity is not satisfactorily resolved within the established timeframe, as determined by the Lab EAG, then the Lab EAG shall recommend the Suspension or ATR of the Laboratory, as applicable. The Laboratory shall remain subject to a Provisional Suspension or provisional ATR until the later of:

   i. The date of the final decision by the Chair of the *WADA* Executive Committee, or

   ii. The date of the final decision rendered by *CAS* should the Laboratory appeal.

   In this instance:

a) No right of challenge to the DC

   The Laboratory has no right to challenge the Lab EAG's recommendation to the DC to impose an ATR or a Suspension against the Laboratory pursuant to this Article 7.1.1.3.

b) Right of appeal to *CAS*

   The Laboratory may appeal to *CAS* (in accordance with Article 7.1.5) the decision by the Chair of the *WADA* Executive Committee to impose an ATR or a Suspension pursuant to this Article 7.1.1.3.

   This right of appeal to *CAS* shall not apply if the final decision rendered by the Chair of the *WADA* Executive Committee is based on the Laboratory's acceptance of the recommendation for an ATR or a Suspension.

#### 7.1.1.4 ATR and Suspension of Accreditation – No Disciplinary Proceedings

If a Laboratory has accumulated the maximum allowed number of penalty points for the EQAS and/or Analytical *Testing* (as per the Points Scale Table described in the *TD* PERF), the Lab EAG shall make a recommendation to the Chair of the *WADA* Executive Committee that the Laboratory be subject to an ATR or Suspension, as applicable and as determined by the Lab EAG. In this instance,

a) No right of challenge to the DC

The Laboratory has no right to challenge the Lab EAG's recommendation to the DC to impose an ATR or a Suspension against the Laboratory pursuant to this Article 7.1.1.4.

b) Right of appeal to *CAS*

The Laboratory may appeal to *CAS* (in accordance with Article 7.1.5) the decision by the Chair of the *WADA* Executive Committee to impose an ATR or a Suspension pursuant to this Article 7.1.1.4.

This right of appeal to *CAS* shall not apply if the final decision rendered by the Chair of the *WADA* Executive Committee is based on the Laboratory's acceptance of the recommendation for an ATR or a Suspension.

#### 7.1.1.5 ATR and Suspension of Accreditation – Disciplinary Proceedings

The Lab EAG may also recommend to the Chair of the *WADA* Executive Committee that a Laboratory be subject to an ATR or a Suspension of the Laboratory's *WADA* accreditation even if the Laboratory has not attained the maximum number of penalty points detailed in the Points Scale Table in the *TD* PERF, but where the Laboratory's other Analytical *Testing* failure(s) and/or other identified nonconformities (as described in Article 7.1.1.1) otherwise justifies that such action be taken to ensure the full reliability and accuracy of Analytical *Testing* and the accurate reporting of test results.

a) Prior to recommending a Laboratory Suspension or an ATR to the Chair of the *WADA* Executive Committee, *WADA* shall notify the Laboratory of the Lab EAG's proposed recommendation. The *WADA* notice letter shall [16]:

i. Offer the Laboratory the opportunity to hold a session with the Lab EAG (upon request by the Laboratory) to discuss the Laboratory's noncompliances on which the sanction recommendation is based.

[16] These provisions do not apply in cases of immediate Provisional Suspension or immediate provisional ATR (see Article 7.1.1.3) or when the Laboratory has accumulated the maximum allowed number of penalty points for the EQAS and/or Analytical *Testing* (see Article 7.1.1.4).

ii. If the Laboratory does not request a session, the Laboratory shall have the opportunity to either accept the Lab EAG's recommendation and/or terms for the Suspension or ATR, or to accept the initiation of disciplinary proceedings in accordance with Article 7.1.3.

b) If the Laboratory does request a session with the Lab EAG, the Laboratory may provide further clarifications or evidence of successfully implemented corrective actions addressing the nonconformities to prevent their reoccurrence in the future.

i. At the end of the discussion session, the Lab EAG shall determine if the explanations and/or additional evidence provided by the Laboratory are sufficient to rescind the proposed recommendation for Suspension of the Laboratory's *WADA* accreditation or for imposition of an ATR.

ii. The Lab EAG shall not recommend a Suspension or ATR if it determines that the explanations and/or additional evidence provided by the Laboratory during the discussion session demonstrate that satisfactory corrective actions have been implemented to address the nonconformities.

iii. If following the discussion session, the Lab EAG determines that the explanations and/or additional evidence provided by the Laboratory are not sufficient to rescind the proposed recommendation for Suspension or for imposition of an ATR, and the Laboratory does not accept the recommendation and/or terms for the Suspension or ATR, disciplinary proceedings will be initiated and conducted in accordance with Article 7.1.3.

c) If the Laboratory does not accept the recommendation, the Lab EAG, based on the seriousness of the Laboratory's Analytical *Testing* failures and/or other identified nonconformities, may issue a recommendation to the Chair of the *WADA* Executive Committee that the Laboratory:

i. Continue its Analytical *Testing* activities pending the outcome of the Laboratory's challenge to the DC, or

ii. Be immediately subject to a Provisional Suspension or be subject to an immediate provisional ATR pending the outcome of the disciplinary proceedings. In such cases, a decision by the Chair of the *WADA* Executive Committee to impose a Provisional Suspension or a provisional ATR shall not be subject to appeal by the Laboratory.

However, should the Laboratory be immediately subject to a Provisional Suspension or a provisional ATR, the proceedings before the DC should be conducted within forty-five (45) days of the date when the Provisional Suspension or provisional ATR was imposed.

d) Right of appeal to *CAS*:

In such circumstances, the Laboratory may appeal to *CAS* (in accordance with Article 7.1.5) the decision by the Chair of the *WADA* Executive Committee to impose an ATR or a Suspension pursuant to this Article 7.1.1.5.

This right of appeal to *CAS* shall not apply if the final decision rendered by the Chair of the *WADA* Executive Committee is based on the Laboratory's acceptance of the recommendation for an ATR or a Suspension.

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

### 7.1.2 Revocation of *WADA* Accreditation

The *WADA* Executive Committee shall revoke a Laboratory's *WADA* accreditation 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.

#### 7.1.2.1 Laboratory Noncompliances Leading to Revocation of *WADA* Accreditation

The Lab EAG shall recommend the Revocation of a Laboratory's *WADA* accreditation based on, but not limited to, the following noncompliance(s):

a) A serious or repeated violation(s) of the ISL Code of Ethics.

b) Conviction of any key personnel for any criminal offence that is determined by *WADA* to impact the operations of the Laboratory.

c) Repeated suspensions of ISO/IEC 17025 accreditation or Suspensions of *WADA* accreditation or repeated impositions of ATRs against the Laboratory.

d) Repeated reporting of False *AAFs* with *Consequences* for *Athletes*.

*[Comment 1 to Article 7.1.2.1 d): The repeated reporting of False AAFs with Consequences for an Athlete(s) shall lead to the Revocation of the Laboratory's WADA accreditation, irrespective of whether those findings were independent as described in the Comment 2 to Article 7.1.1.1 f).]*

e) Repeated accumulation of the maximum allowed number of penalty points for the EQAS and/or Analytical *Testing* as determined by the application of the Points Scale Table described in the *TD* PERF.

f) Repeated reporting of False *AAFs* or repeated failure to implement satisfactory corrective action(s) after the reporting of a False *AAF*.

g) Repeated reporting of False Negative Findings or repeated failure to implement satisfactory corrective action(s) after the reporting of False Negative Finding(s).

h) Failure to correct a noncompliance with any of the requirements or standards listed in the ISL and/or *TD*s and/or *TL*s by the end of the initial or extended Suspension period in accordance with Article 7.3.

i) Repeated failure to comply with the ISL and/or *TD*s and/or *TL*s.

j) Serious Laboratory noncompliance(s) with the ISL and/or *TD*s and/or *TL*s identified, for example, during *WADA* Laboratory assessments, by documented client complaints or through other enquiries or investigations conducted by *WADA*.

k) Repeated failure to implement satisfactory corrective action(s) following unsatisfactory performance either in routine Analytical *Testing* or in a blind EQAS or double-blind EQAS round.

l) Repeated failure to implement satisfactory corrective action(s) following ISL and/or *TD* and/or *TL* noncompliance(s) identified from *WADA* Laboratory assessment(s).

m) Repeated failure to analyze the minimum number of *Samples* indicated in Article 4.1.4.2.8.

n) Continuous and 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).

o) Failure to cooperate with *WADA* or any relevant TA or RMA during a Suspension or ATR period.

p) Analysis of *Samples* from *Signatories* in violation of a Suspension or ATR decision.

q) Repeated and/or continuous failure to cooperate in any *WADA* inquiry in relation to the activities of the Laboratory.

r) Repeated failure to implement and document adequate R&D and Sharing of Knowledge activities.

s) Continuous failure to establish/maintain administrative and operational independence (see Article 4.1.4.2.5), as determined by *WADA*.

t) Loss of support which significantly affects the quality and/or viability of the Laboratory, and/or

u) 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.

#### 7.1.2.2 Revocation Procedures - Laboratory Not Under ATR or Suspension

a) Prior to recommending the Revocation of a Laboratory's *WADA* Accreditation to the *WADA* Executive Committee, *WADA* shall notify the Laboratory of the Lab EAG's proposed recommendation.

b) Upon request by the Laboratory, *WADA* shall offer the Laboratory the opportunity to hold a session with the Lab EAG to discuss the Laboratory's noncompliances on which the Revocation recommendation would be based.

During this session, the Laboratory may provide further clarifications or evidence of successfully implemented corrective actions addressing the nonconformities to prevent their reoccurrence in the future.

If the Laboratory does not request a session, the Lab EAG shall offer the Laboratory the opportunity to either accept the Lab EAG's recommendation and/or terms for the Revocation or to initiate disciplinary proceedings in accordance with Article 7.1.3.

c) At the end of the discussion session, the Lab EAG shall determine if the explanations and/or additional evidence provided by the Laboratory are sufficient to rescind the recommendation for Revocation of the Laboratory's *WADA* accreditation.

i. The Lab EAG shall withdraw the recommendation for Revocation, or any other Laboratory sanction, if it determines that the explanations and/or additional evidence provided by the Laboratory during the discussion session demonstrate that adequate and satisfactory corrective actions have been implemented to address the nonconformities and avoid their recurrence in the future.

ii. If, following the discussion session, the Lab EAG determines that the explanations and/or additional evidence provided by the Laboratory are not sufficient to rescind the recommendation for Revocation, the Lab EAG shall maintain the recommendation for Revocation to the *WADA* Executive Committee and, additionally, recommend to the Chair of the *WADA* Executive Committee that the Laboratory's *WADA* accreditation be immediately subject to a Provisional Suspension pending the outcome of the disciplinary proceedings conducted pursuant to Article 7.1.3. In such cases, a decision by the Chair of the *WADA* Executive Committee to impose a Provisional Suspension against the Laboratory shall not be subject to appeal by the Laboratory. However, should the Laboratory be immediately subject to a Provisional Suspension, the proceedings before the DC should be conducted within forty-five (45) days of the date when the Provisional Suspension of the Laboratory's *WADA* accreditation was imposed.

d) Right of challenge to the DC:

If the Laboratory does not accept the Lab EAG's recommendation for Revocation, the Laboratory may challenge the Lab EAG's recommendation to the DC and disciplinary proceedings will be conducted in accordance with Article 7.1.3.

e) Right to appeal to *CAS*:

A Laboratory may appeal a decision by the *WADA* Executive Committee to revoke its *WADA* accreditation to *CAS* in accordance with Article 7.1.5.

This right of appeal shall not apply if the final decision rendered by the Chair of the *WADA* Executive Committee is based on the Laboratory's acceptance of the recommendation for Revocation.

#### 7.1.2.3 Revocation Procedures – Laboratory Under ATR or Suspension

a) If the Laboratory is already subject to an ATR or Suspension at the commencement of Revocation procedures, *WADA* will notify the Laboratory of the Lab EAG's recommendation for Revocation with an option for the Laboratory to either accept or challenge the terms of the recommendation to the DC, without an opportunity for the Laboratory to hold a discussion session with the Lab EAG.

b) *WADA* will notify the Executive Committee of the Lab EAG's recommendation for Revocation.

c) If the Laboratory does not accept the Lab EAG's recommendation for Revocation, disciplinary proceedings will be conducted in accordance with Article 7.1.3.

d) A Laboratory may appeal a decision by the *WADA* Executive Committee to revoke its *WADA* accreditation to *CAS* in accordance with Article 7.1.5. This right of appeal to *CAS* shall not apply if the final decision rendered by the *WADA* Executive Committee is based on the Laboratory's acceptance of the Lab EAG's recommendation for Revocation.

### 7.1.3 Disciplinary Proceedings

In the event that a Laboratory challenges the Lab EAG's recommendation for an ATR or Suspension, in accordance with Article 7.1.1.5, or recommendation for Revocation, in accordance with Articles 7.1.2.2 or 7.1.2.3, *WADA* shall constitute an impartial DC in accordance with Article 1 of the Procedural Rules (see Annex A). 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 related to the Lab EAG's ATR, Suspension or Revocation recommendation. The Laboratory shall be permitted to make written submissions and provide any supporting documents or evidence in accordance with Article A-3 of the Procedural Rules (Annex A).

The DC shall issue a recommendation to the Chair of the *WADA* Executive Committee or, where applicable (e.g., in the case of a Revocation), to the *WADA* Executive Committee, regarding the action(s) to be taken regarding the Laboratory's *WADA* accreditation in accordance with the requirements and procedure described in Article A-7 of the Procedural Rules (Annex A).

*[Comment 1 to Article 7.1.3: For the avoidance of doubt, and as indicated in 7.1.1.3 and 7.1.1.4, disciplinary proceedings will not be conducted pursuant to this Article 7.1.3 in situations where the Lab EAG recommends the imposition of an ATR or the Suspension of a Laboratory's WADA accreditation due to the Laboratory's failure to satisfactorily resolve a nonconformity(-ies) that led to the reporting of a False AAF with Consequence(s) for an Athlete within the established timeframe, or if a Laboratory accumulated the maximum allowed number of penalty points for the EQAS and/or Analytical Testing (as determined by the application of the Points Scale Table described in the TD REF). Instead, and only in the aforementioned circumstances, the Laboratory may appeal any decision of the Chairman of the WADA Executive Committee to impose an ATR or to suspend the Laboratory's WADA accreditation directly to CAS in accordance with Article 7.1.5.]*

### 7.1.4 Notification of Decision

Upon completion of the procedures indicated in Article 7.1.3, or the exceptions described in Articles 7.1.1.3 and 7.1.1.4, as applicable, and in accordance with the timelines indicated in Article A-7 of the Procedural Rules (Annex A), *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:

a) That the Laboratory's *WADA* accreditation has been maintained (including warnings and/or conditions, if applicable), or

b) That the Laboratory's *WADA* accreditation has been suspended or revoked or that an ATR has been imposed against the Laboratory.

Such notice shall include:

a) The reason(s) for Suspension or Revocation or the imposition of an ATR.

b) The terms of the Suspension, Revocation, or ATR, and

c) The period of the Suspension or ATR, if applicable.

For proceedings conducted pursuant to Article 7.1.3, *WADA* shall also provide the Laboratory with a copy of the DC's recommendation.

### 7.1.5 Effective Date and Appeals

a) A Suspension or ATR is effective immediately upon receipt of notification of the decision.

b) A Revocation takes effect one (1) month after notification. The Laboratory shall remain under Provisional Suspension or 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.

c) A Laboratory may appeal a decision by *WADA* to revoke or suspend its *WADA* accreditation, or to impose an ATR, to *CAS* in accordance with *Code* Article 13.7.

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

#### 7.1.6 Public Notice

a) *WADA* shall publicly announce a change in a Laboratory's accreditation status on its website as soon as the Laboratory is notified by *WADA* of its decision. In cases of Laboratory Revocation, the public notice shall specify that the Laboratory shall remain under Provisional Suspension or Suspension until the date when the Revocation becomes effective, as determined in Article 7.1.5.

b) *WADA* shall also indicate the terms and length of the Suspension or the ATR. In the case of an ATR, the relevant impacted Test Method or *Prohibited Substance*/*Prohibited Method* class shall be detailed.

c) *WADA*'s website shall be updated regarding a Laboratory's accreditation status when the Laboratory's *WADA* accreditation is reinstated following a Suspension or when an ATR is lifted.

### 7.2 Consequences of Suspended or Revoked Accreditation or ATR

During a Suspension or ATR period, the Laboratory shall continue to participate in the *WADA* EQAS program. *WADA* may require the Laboratory to analyze additional blind EQAS samples and/or perform a Laboratory assessment, at any time and at the expense of the Laboratory, to evaluate the Laboratory's status.

#### 7.2.1 ATR

If *WADA* determines that the noncompliance(s) are limited to a class of *Prohibited* Substances or *Prohibited Methods* or to a specific Analytical *Testing* Procedure, which are not included in the standard Analytical *Testing* menu for *IC* or *OOC Samples*, *WADA* may impose an ATR for that class of *Prohibited Substance(s)* or *Prohibited Method(s)* or for the specific Analytical *Testing* Procedure in which the noncompliance(s) occurred.

Following the ATR notification by *WADA*, the Laboratory shall:

a) Inform its clients of the imposed ATR.

b) Immediately cease all analyses employing the affected Analytical *Testing* Procedure(s).

c) Subcontract the affected analyses to another Laboratory(-ies), in consultation with the relevant TA, during the period of the ATR, as provided in Article 5.2.6.

d) Transfer [17] the following *Samples* ("A" and "B" *Samples*) in the Laboratory's custody, which may be affected by the ATR conditions (i.e., involving the analysis

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

of the same class of *Prohibited Substances* or *Prohibited Methods* and/or the application of the Analytical *Testing* Procedure(s) subjected to the ATR) to a subcontracted Laboratory(-ies) for the performance of the "A" and, if needed, the "B" CPs (unless otherwise instructed by *WADA*). The Laboratory shall inform *WADA* of the relevant TA(-ies) and the subcontracted Laboratory(-ies).

i. *Samples* which had been previously reported as an *AAF*.

ii. *Samples* with confirmed but not reported *AAF* or *ATF*;

iii. *Samples* with non-confirmed PAAFs;

iv. *Samples* with ongoing ITP or CP analysis.

e) If the ATR was caused by the reporting of False Negative Finding(s), and further investigation reveals that other *Samples* reported as Negative Finding(s) and still stored in the Laboratory may have been impacted, the Laboratory shall inform the TA and *WADA*.

In such cases, both the "A" and "B" containers of the relevant *Samples* shall be transferred [17] to a subcontracted Laboratory(-ies) for Further Analysis, as determined by *WADA*. The Further Analysis may 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*.

### 7.2.2 Suspension of *WADA* Accreditation

A Laboratory whose *WADA* accreditation has been suspended is ineligible to perform Analytical *Testing* of *Samples* for any *Signatory*. This provision does not apply when the noncompliance(s) that led to the Suspension does not impact the blood analyses for the *ABP*, as determined by *WADA*.

The Laboratory shall take the relevant steps following the notification of a *WADA* Suspension decision:

a) Cease all Analytical *Testing* immediately.

b) Inform *WADA* of the *Sample* codes and relevant TA(-ies) for all *Samples* in the Laboratory's custody.

c) Maintain all *Samples* in the Laboratory's custody under proper LCOC and appropriate storage conditions.

The Laboratory shall not dispose of any *Sample* without the written approval of *WADA*. The Laboratory shall provide *WADA* with the *Sample* codes and relevant TA(-ies) for all *Samples* in storage.

d) Irrespective of the cause that led to the Suspension, the Laboratory shall transfer the following *Samples* ("A" and "B") to a subcontracted Laboratory(-ies) for the

performance of the "A" (ITP and CP, if needed) and "B" analysis (if requested), unless otherwise instructed by *WADA* [18]:

i. *Samples* with confirmed but not yet reported *AAF* or *ATF*;

ii. *Samples* with non-confirmed PAAFs;

iii. *Samples* which ongoing ITP or CP analysis;

iv. *Samples* which had been received at the Laboratory but had not been opened.

e) Suspension for Violation of the ISL Code of Ethics

The Laboratory shall transfer [18] all *Samples* (both the "A" and "B" *Samples*) in the Laboratory's custody to another Laboratory(-ies) chosen by the TA(-ies).

f) Suspension for Reporting of False *AAF(s)*

The Laboratory shall transfer [18] *Samples* previously reported as an *AAF*, which may have been affected by the False *AAF* condition (i.e., involving the same class of *Prohibited Substances* or *Prohibited Methods* analyzed with the same CP).

g) Suspension for Reporting False Negative Finding(s)

i. If *Samples* were undergoing ITP analysis, or if the ITPs had been completed with negative results, but the results had not been reported, both the "A" and "B" *Samples* shall be transferred [18] to another Laboratory(-ies) to reconduct the ITPs and, if needed, to perform the CPs. 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.*

ii. If the Laboratory's investigation reveals that other *Samples* already reported as Negative Finding(s) may have been impacted (including *Samples* that have been placed in long-term storage upon request by the TA or *WADA*), the Laboratory shall inform the TA and *WADA*. In such cases, both the "A" and "B" containers of the relevant *Samples* shall be transferred [18] to a subcontracted Laboratory(-ies) for Further Analysis. The Further Analysis may be applied for all the *Prohibited Substances* and *Prohibited Methods* included in the requested *Testing* menu or be limited to the class of *Prohibited Substances*

[18] The suspended or revoked Laboratory shall contact the relevant TA(-ies) to arrange for the transfer of *Samples* to another Laboratory(-ies), chosen by the TA, within thirty (30) days of being notified of the Suspension or Revocation decision. Any additional costs of analysis to those previously agreed or already paid to the suspended or revoked Laboratory shall be borne by the Laboratory under Suspension or Revocation. In the case of ISL Code of Ethics violation(s), the suspended or revoked Laboratory shall also reimburse the TA 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 TA(-ies) and the chosen Laboratory(-ies). TAs 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 TA may consult the Laboratories implicated and/or *WADA* for guidance.

and/or *Prohibited Methods* or to the Analytical *Testing* Procedure(s) that were associated with the Negative Finding(s), as determined by *WADA.*

h) Suspension for Other Reasons

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

i. *Samples* for which ITPs had been completed with negative results, but results had not been reported:

The *Sample*(s) result shall be reported in *ADAMS* as Negative Finding(s). The Laboratory shall inform *WADA*, including the provision of the *Sample* codes and the identity of the relevant TA(-ies).

ii. *Samples,* which had been reported as an *AAF* based on the "A" CP only:

Should a "B" CP be requested during the Suspension, both "A" and "B" *Samples* shall be transferred [18] to another Laboratory(-ies) for the "A" CP to be repeated and to perform the "B" CP, if applicable.

i) Suspension Related to Blood *ABP* Analysis

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

*[Comment to Article 7.2.2 i): 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 analysis within an acceptable timeframe.]*

### 7.2.3 Revocation of *WADA* Accreditation

a) A laboratory whose *WADA* accreditation has been revoked is ineligible to perform Analytical *Testing* of *Samples* for any *Signatory*.

b) The LCOC maintained by a revoked laboratory for stored *Samples* is valid until such time that arrangements can be made, in consultation with *WADA* and the associated TA(-ies), for the transfer [18] of the relevant *Samples* to a Laboratory(-ies).

c) A revoked laboratory shall arrange the transfer [18] of *Samples* in the laboratory's custody to a Laboratory(-ies) chosen by the TA(-ies) or *WADA* within thirty (30) days of being notified of the decision to revoke its *WADA* accreditation.

i. In such circumstances, the *Samples* to be transferred shall be selected by the TA or *WADA*. The laboratory transferring the *Samples* shall inform *WADA* and

provide the relevant *Sample* codes and the identity of the relevant TA(-ies) and the chosen Laboratory(-ies).

ii. In addition, the revoked laboratory shall assist the relevant TA(-ies) with the transfer of the relevant *Sample* data and records to the Laboratory(-ies) that have been selected to receive the *Samples* (see Article 5.4.4).

d) The revoked laboratory shall transfer all *Samples* in its custody for which the Analytical *Testing* has not been completed at the time of the Revocation. In addition, the laboratory shall consult TA(-ies) on whether additional *Samples* already analyzed and retained in the laboratory, for which the TA is the owner pursuant to Article 10.1 of the IST, shall also be transferred or disposed. Furthermore, *WADA* may also identify and request that *Samples* be transferred to another Laboratory(-ies).

### 7.3 Extension of Suspension or Analytical *Testing* Restriction

a) If a Laboratory has not satisfactorily corrected the noncompliance(s) that resulted in their Suspension or ATR or if *WADA* identifies any additional ISL and/or *TD* and/or *TL* noncompliance(s) during the initial Suspension or ATR period of six (6) months (for example, during a *WADA* Laboratory assessment):

i. The Laboratory's Suspension or ATR may be extended, or

ii. Suspension proceedings may be initiated (if the Laboratory was subject only to an ATR), or

iii. Revocation proceedings may be initiated, as determined by *WADA.*

b) The Suspension or ATR period may be extended up to an additional six (6) months, if the Laboratory provides justifiable explanation(s), as determined by the *WADA*, in addressing the conditions to lift the Suspension or ATR (including the submission of satisfactory corrective actions). The Suspension or ATR, including any extensions, shall not exceed twelve (12) months, unless the Laboratory is subject to Revocation proceedings in accordance with Article 7.1.2 or as otherwise determined by *WADA*.

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

c) The decision to extend the Suspension or the ATR period shall be rendered by the Chair of the *WADA* Executive Committee based on a recommendation from the Lab EAG. *WADA* will provide the Laboratory with the decision of the Chair of the *WADA* Executive Committee.

d) The Laboratory may appeal *WADA*'s decision not to extend the Suspension or the ATR period to *CAS* in accordance with Article 7.1.5.

e) If, in accordance with the terms of the extension of the Suspension or the ATR, the Laboratory provides evidence determined to be satisfactory by *WADA* that all the identified noncompliance(s) have been corrected, the Suspension or ATR shall be lifted by decision of the Chair of the *WADA* Executive Committee.

f) If the Laboratory has not provided evidence determined to be satisfactory by *WADA* at the end of the extended Suspension period, the Lab EAG shall recommend the Revocation of the Laboratory's accreditation. The decision to revoke a Laboratory's *WADA* accreditation shall be rendered by the *WADA* Executive Committee.

g) If the Laboratory has not provided evidence determined to be satisfactory by *WADA* at the end of the extended ATR period, the Lab EAG shall recommend the Suspension or Revocation of the Laboratory's accreditation, as determined by the Lab EAG. The decision to suspend a Laboratory's *WADA* accreditation shall be rendered by the Chair of the *WADA* Executive Committee, whereas a *WADA* accreditation Revocation decision shall be rendered by the *WADA* Executive Committee.

h) If the Laboratory is subject to Suspension proceedings either at the end of a six (6) month ATR or any extension thereafter, the Laboratory's accreditation shall remain subject to the ATR or a Provisional Suspension (if applicable) until the completion of the Suspension proceedings.

i) If the Laboratory is subject to Revocation proceedings either at the end of a six (6) month Suspension or ATR or any extension thereafter, the Laboratory's *WADA* accreditation shall remain subject to the Suspension or ATR, as applicable, until the completion of the Revocation proceedings and pending the Revocation decision by the *WADA* Executive Committee. If the *WADA* Executive Committee confirms the Revocation of the Laboratory's *WADA* accreditation, then the Laboratory's *WADA* accreditation shall remain subject to the Suspension or ATR, as applicable, until the Revocation comes into effect according to Article 7.1.5.

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

### 7.4 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 ATR 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 its 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, the transfer of *Samples* to another Laboratory(-ies).

a) Temporary Closure of Laboratory Operations

i. If a Laboratory voluntarily ceases its anti-doping Analytical *Testing* operations on a temporary basis, the Laboratory shall:

- Transfer *Samples* to another Laboratory(-ies) in accordance with Article 7.2.2;
- Maintain its participation in the *WADA* EQAS with satisfactory performance during the period of inactivity.

ii. The period of temporary cessation of Analytical *Testing* activities shall not exceed six (6) months, unless reasons are provided by the Laboratory justifying the possible extension of up to six (6) additional months (as determined by the Chair of the *WADA* Executive Committee based on a recommendation from the Lab EAG).

iii. If the Laboratory is unable to resume its Analytical *Testing* operations within a twelve (12)-month period, the *WADA* Executive Committee shall revoke the Laboratory's accreditation, unless otherwise determined by *WADA*.

b) Permanent Closure of Laboratory Operations

If a Laboratory decides to cease its operations on a permanent basis, the Laboratory shall assist the relevant TA(-ies) with the transfer of relevant *Sample* data and records to another Laboratory(-ies) in accordance with Article 7.2.3.

## 7.5 Laboratory Reinstatement

### 7.5.1 Reinstatement of Suspended Accreditation or Lifting of ATR

*WADA* shall lift the Suspension of the Laboratory's *WADA* accreditation or the ATR 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 ATR, respectively, and that proper measures have been implemented to satisfactorily address the condition(s) specified, if any, for reinstatement of its *WADA* accreditation.

### 7.5.2 Reaccreditation after Revocation

If a laboratory whose *WADA* accreditation has been revoked wishes to seek a new *WADA accreditation*, it must apply for *WADA* accreditation as a new laboratory in accordance with Article 4.1.1.

A laboratory seeking a new *WADA* accreditation, may request that *WADA* expedite the laboratory re-accreditation process. To do so the laboratory shall provide *WADA*, as part of its *application* for a new accreditation, information that it considers constitutes "exceptional circumstances" to justify modification of the requirements of Articles 4.1.1 and 4.1.2 and 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 an expedited re-accreditation process.

## 7.6 Suspension or Revocation of *ABP* Laboratory

A laboratory's *WADA* approval for the *ABP* may be suspended or revoked whenever the *ABP* Laboratory fails to comply with the ISL and/or applicable *TD*s and/or *TL*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.

a) Suspension and Revocation procedures for an *ABP* Laboratory's approval status shall follow the provisions of Articles 7.1.1.5 and 7.1.2.2, respectively, *mutatis mutandis*.

b) Disciplinary proceedings to suspend or revoke a laboratory's *WADA* approval for the *ABP* (including notice, publication, and right to appeal) shall be conducted in accordance with the procedures described in Article 7.1.3, applied, and modified accordingly, and the Procedural Rules (Annex A).

c) 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) or *ABP* Laboratory(-ies) for analysis after Suspension or Revocation of a laboratory's *WADA* approval for the *ABP*.

d) *WADA* shall lift the Suspension of laboratory's *WADA* approval for the *ABP* 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* approval for the *ABP*, and that proper measures have been implemented to satisfactorily address the condition(s) specified, if any, for reinstatement of *WADA* approval.

If a laboratory whose *WADA* approval for the *ABP* has been revoked wishes to seek a new *WADA* approval, it must apply for *WADA* approval for the *ABP* as a new laboratory in accordance with Article 4.2.1.

## 7.7 Reporting of False Analytical Findings During a Major *Event*

a) Reporting of a False *AAF*

If a Laboratory reports a False *AAF* during a Major *Event*, the Laboratory shall:

i. Immediately cease the application of the relevant Analytical *Testing* Procedure(s) (immediate provisional ATR).

ii. Inform the *MEO*.

iii. Determine the root cause of the nonconformity within twenty-four (24) hours of notification of the False *AAF.*

iv. Apply and report to *WADA* satisfactory corrective action(s) within forty-eight (48) hours of notification of the False *AAF*, unless otherwise agreed in writing.

v. Re-analyze all *Samples* that had been analyzed prior to the reporting of the False *AAF* and reported as an *AAF* with the Analytical *Testing* Procedure(s) for which the noncompliance occurred. The results of the investigation and analysis shall be presented to *WADA* within forty-eight (48) hours, unless otherwise agreed in writing.

b) Reporting of a False Negative Finding

If a Laboratory reports a False Negative Finding during a Major *Event*, the Laboratory shall:

i. Inform the *MEO*.

ii. Investigate the root cause and apply satisfactory corrective actions as soon as possible.

iii. Re-analyze an appropriate number of *Samples* reported as a Negative Finding with the Analytical *Testing* Procedure(s) for which the noncompliance occurred.

iv. The corrective actions implemented, and the results of the re-analysis shall be presented to *WADA* within forty-eight (48) hours, unless otherwise agreed in writing.

The failure by the Laboratory to implement satisfactory corrective action(s) in a timely manner, as specified above, will result in the imposition of a Suspension or an ATR, as determined by *WADA*, and the cessation of Analytical *Testing* during the Major *Event*. The procedure for the imposition of a Suspension or an ATR shall follow the provisions of Article 7.1.1.5 *mutatis mutandis*.

## 8.0 Code of Ethics for Laboratories and *ABP* Laboratories

### 8.1 Confidentiality

Directors of Laboratories and *ABP* Laboratories, their delegates and all Laboratory staff shall respect and comply with Article 5.3.6.3 and *Code* Article 14.3.6.

### 8.2 Research in Support of *Doping Control*

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

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

#### 8.2.1 Research on Human Subjects

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

*Athletes* who may undergo *Doping Control Testing* by *ADO*s shall not be the subjects of drug administration studies that include *Prohibited Substances* or *Prohibited Method*s.

#### 8.2.2 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.

### 8.3 Analysis

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

*[Comment to Article 8.3: The World Anti-Doping Program comprises the anti-doping programs of WADA and all Signatories, including International Federations, NADOs, RADOs, MEOs, the International Olympic Committee (IOC) or the International Paralympic Committee (IPC).]*

#### 8.3.1 Analytical *Testing* for *ADO*s

The Laboratories and *ABP* Laboratories shall accept *Samples* for Analytical *Testing* from *ADO*s only if all the following conditions have been met:

a) The *Sample* matrix is of the proper type (e.g., blood, urine, DBS) for the requested analyses.

b) The *Samples* have been collected, sealed, and transported to the Laboratory or *ABP* Laboratory in accordance with the *International Standard* for *Testing* (IST); and

c) The collection is a part of a legitimate anti-doping program, as determined by *WADA*, or satisfies any of the conditions for *Sample* analysis indicated in Article 5.3.4.2.

### 8.3.2 Analytical *Testing* for non-*Signatories*

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

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

*[Comment to Article 8.3.2: A Laboratory or ABP Laboratory shall only refer to its WADA accreditation or approval status, as applicable, for an activity that falls under its Analytical Testing activities for ADOs. For the avoidance of doubt, laboratory test reports or other documentation or correspondence related to samples from non-Signatories shall not declare or represent that any such testing is covered under the laboratory's WADA-accredited or -approved status].*

### 8.3.3 Clinical or Forensic Analysis

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

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

### 8.3.4 Other Analytical Activities

The Laboratory or *ABP* Laboratory shall not provide analytical services in a *Doping Control* adjudication, unless specifically requested by the responsible TA or RMA, *WADA* or a hearing body.

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

a) Specifically requested by an *ADO* or a hearing body as part of a *Results Management* or adjudication process; or

b) If done as part of a legitimate anti-doping research program, as determined by *WADA*; or

c) If a request is made by an *Athlete*, the Laboratory may conduct the analysis if agreed by the *ADO*, which may also specify conditions that must be followed prior to or during the analysis (e.g., verification of original sealed packages, product batch number).

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

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

*[Comment to Article 8.3.4: For the avoidance of doubt, laboratory test reports or other documentation or correspondence related to these other analytical activities shall not declare or represent that any such testing is covered under the laboratory's WADA-accredited or -approved status.]*

## 8.4 Sharing of Knowledge

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

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

*[Comment to Article 8.4: 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 RM(s) or RC(s) or disseminating analytical protocols or information.]*

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

a) The personnel of Laboratories and *ABP* Laboratories shall not engage in conduct or activities that undermine or are detrimental to the World Anti-Doping Program or *WADA*. 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. This also pertains to any attempts of collusion between Laboratories, Probationary laboratories and/or *ABP* Laboratories as part of their participation in the *WADA* EQAS (see also *TD* EQAS).

b) All employees of Laboratories and *ABP* Laboratories shall strictly respect the confidentiality of Analytical *Testing* results, as well as of all other Laboratory or TA information, including information provided by *WADA* under confidentiality.

c) No employee or consultant of Laboratories and *ABP* Laboratories shall provide counsel, advice or information to *Athletes* or others regarding techniques or methods used to mask or avoid detection of, alter metabolism of, or suppress excretion of a *Prohibited Substance* or its *Metabolite(s)*, or *Marker*(*s)* of a *Prohibited Substance* or *Prohibited Method* to avoid an *AAF*.

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

*[Comment to Article 8.5 d): This does not prohibit the publication and/or presentation of scientific research results, general presentations to educate Athletes, students, or others concerning anti-doping programs and Prohibited Substances or Prohibited Methods.]*

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

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

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

### 8.6 Breach and Enforceability

A failure to respect any of the provisions of this Code of Ethics may result in the Laboratory or *ABP* Laboratory being subject to Disciplinary Proceedings instituted by *WADA* to either suspend or revoke its *WADA* accreditation or its *WADA* approval, as applicable, in accordance with ISL Article 7.1.3.

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

# PART THREE: ISL ANNEX

# ISL ANNEX A – PROCEDURAL RULES FOR THE DISCIPLINARY COMMITTEE OF THE ISL

### Preamble

These Procedural Rules for the Disciplinary Committee (DC) of the ISL (the "Procedural Rules") outline the process to be followed when a Laboratory challenges a recommendation of the Lab EAG in accordance with ISL Article 7.1.1.5, when a Laboratory is subject to Revocation proceedings in accordance with ISL Article 7.1.2.2 or, when and where applicable, disciplinary proceedings are instituted against an *ABP* Laboratory in accordance with ISL Article 7.6. In such circumstances, any reference made to a Laboratory in these Procedural Rules shall also be understood as a reference to an *ABP* Laboratory, unless such reference is not applicable due to the circumstances, specific nature or rules indicated in this ISL in relation to *ABP* Laboratories.

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

### PART I – Composition of the Committee

#### *Article A-1*

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

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

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

All appointed members of a DC shall be free of any conflict of interest with *WADA*, the Laboratory concerned, or any other Laboratory, entity, organization, or individual that could potentially benefit from the concerned Laboratory's Suspension, Revocation or ATR, 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 Lab EAG unless the case has been the subject of previous discussion or recommendation by the Lab EAG.

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

#### *Article A-2*

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

## PART II – General Provisions

### *Article A-3*

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

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

Within seven (7) days of receiving the case file, the Laboratory may respond in writing and provide its evidence to the DC and simultaneously to *WADA*'s Legal Department. Any requests to extend the deadline shall be addressed by the Laboratory to the Chairperson of the DC, who shall have the discretion to grant or reject the requested extension.

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

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

### *Article A-4*

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

### *Article A-5*

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

## PART III – Scope of the Committee's Review

### *Article A-6*

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

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

The DC shall have the right to appoint one or more independent expert(s) should it consider that 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 ATR.

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

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

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

## PART IV – Recommendation

### *Article A-7*

The recommendation of the DC shall be issued in writing, with reasons [19], within fourteen (14) days of the conclusion of the hearing. If no hearing is held, the DC shall issue its recommendation within fourteen (14) days of the communication to the parties that no hearing will be held.

Where the DC considers that a Laboratory's accreditation should be suspended or subject to an ATR, it shall recommend to the Chair of the *WADA* Executive Committee a period of Suspension or ATR that is proportionate to the seriousness of the noncompliance(s) with the ISL and/or *TDs* and/or *TL*s and the need to ensure accurate and reliable Analytical *Testing* of *Samples*.

The DC may recommend to the Chair of the *WADA* Executive Committee that a Laboratory's *WADA* accreditation be suspended or subjected to an ATR for a period of up to six (6) months. During this time, any ISL and/or *TD* and/or *TL* 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 ATR, or during a subsequent assessment conducted by *WADA* during the Laboratory's Suspension or during the period of the ATR, shall be corrected, documented, reported to *WADA* and determined to be satisfactory by *WADA.* The DC shall also indicate any conditions that the Laboratory shall satisfy prior to or after reinstatement of the Laboratory's *WADA* accreditation.

In cases where it considers that it is appropriate to do so, the DC may also recommend to the Chair of the *WADA* Executive Committee that the Laboratory receive a private warning without the imposition of a period of Suspension or ATR. The Laboratory may also be requested to take specified action(s) to resolve the issues identified within a defined timeline.

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

If the DC recommends the Suspension of the Laboratory's *WADA* accreditation or the imposition of an ATR, the Chair of the *WADA* Executive Committee shall render a final decision regarding the Suspension of the Laboratory's *WADA* accreditation or the imposition of an ATR within ten (10) days of receiving the DC's recommendation.

[19] The decision may be summarily reasoned.

If the DC recommends the Revocation of the Laboratory's *WADA* accreditation, the *WADA* Executive Committee shall render a decision regarding the Revocation of the Laboratory's *WADA* accreditation within fourteen (14) days of receiving the DC's recommendation.

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

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

### *Article A-8*

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

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

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

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

*[Comment to Article A-8: The Laboratory or WADA may request that disciplinary proceedings be conducted in an expedited manner if a decision regarding the status of the Laboratory's WADA accreditation must be made shortly prior to the commencement of a Major Event or Event or if otherwise justified by the circumstances.]*

### *Article A-9*

The Laboratory and *WADA* may agree to have the assertion of a noncompliance(s) with the ISL and/or *TD*s and/or *TL*s heard in a single hearing directly before a three (3)-member Panel of the *CAS* Anti-Doping Division in accordance with the Arbitration Rules for the *CAS* Anti-Doping Division.

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