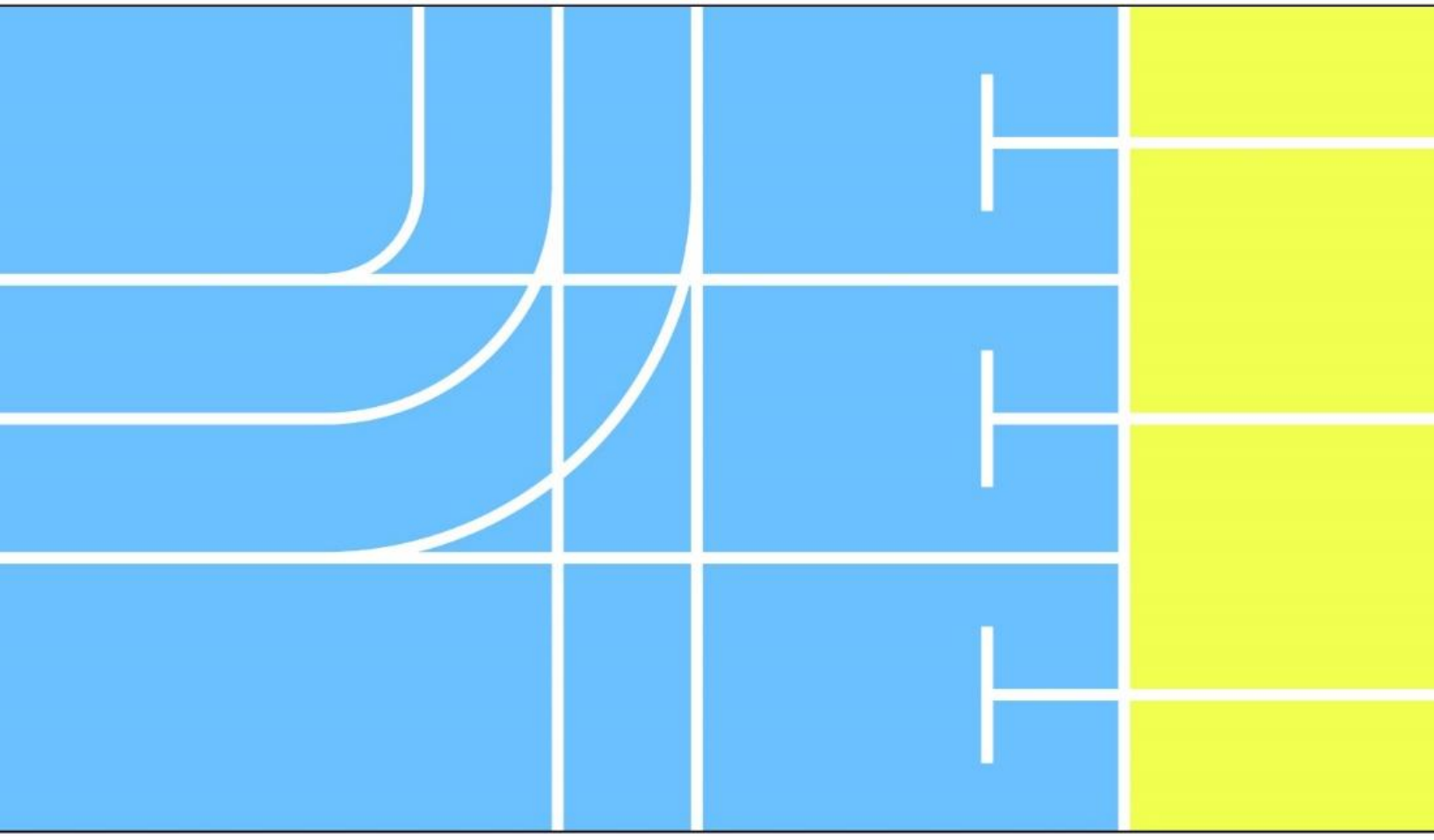
wada

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, *Athletes*, and other relevant *WADA* stakeholders.

The *International Standard* for Laboratories first came into effect in November 2002. It was subsequently amended multiple times, in the years 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 came into force on 1 January 2027.

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Table of Contents

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

1.0 Introduction and Scope

1.1 *WADA* Laboratory Standards

1.1.1 *International Standard* for Laboratories

The main purpose of the *International Standard* for Laboratories (ISL) is to ensure that "Laboratories" (i.e., *WADA*-accredited Laboratories and *WADA*-approved *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 the *Markers* of the Hematological Module of the *Athlete Biological Passport* (*ABP*) by both Laboratories and *ABP* Laboratories.

The ISL sets out the requirements to be followed by 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. The ISL also sets out requirements and guidance for *Anti-Doping Organizations* (*ADO*s) in relation to *Sample* custody and storage, Analytical *Testing* and some aspects of *Results Management*.

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

1.1.2 ISL *Technical Documents*

ISL *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. ISL *TDs* are modified and/or withdrawn by *WADA* as appropriate.

a) Approval and Publication of ISL *TD*s

A stakeholder consultation (including Laboratories, where applicable) shall be conducted for new ISL *TD* drafts.

i. The stakeholder consultation may not be needed for a revised draft of an existing ISL *TD*, as determined by *WADA*. This may include when

the implementation of the revised ISL *TD* is time sensitive (for example, to avoid detrimental *Consequences* on *Athletes*) or when low-impact editorial changes are needed (e.g., correction of typographical errors, formatting changes). Nevertheless, any such revisions of ISL *TDs* shall be reviewed and accepted by the Laboratory Expert Advisory Group (Lab EAG) before the presentation of the new ISL *TD* version to the *WADA* Executive Committee for approval.

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

b) Implementation of ISL *TD*s

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

ii. The implementation of ISL *TD* requirements into the Laboratory's Management System is mandatory for obtaining and maintaining *WADA* accreditation or approval, as applicable, and for the application of the relevant Analytical *Testing* Procedure(s) (ATP) to the analysis of *Samples*.

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

iv. If a Laboratory is not able to implement a new ISL *TD* by its effective date, it shall inform its customers and *WADA* as soon as possible. The 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 ISL *TD*, any measures taken to ensure that *Samples* received in the Laboratory will be subject to Analytical *Testing* in compliance with the new ISL *TD* (for example, by subcontracting the analysis to another Laboratory), as well as plans for the implementation of the new ISL *TD*.

v. A failure by a Laboratory to implement an ISL *TD* by the effective date may result in the imposition of an Analytical *Testing* Restriction (ATR) against the Laboratory for that particular ATP 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 Laboratory's approval for the analysis of the *Markers* of the Hematological Module of the *ABP*, as determined by *WADA*.

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

[Comment to Article 1.1.2 b): The effective date for implementation of an ISL TD shall be interpreted as the deadline, following approval and publication of the ISL TD, by which the ISL TD shall be implemented by Laboratories. However, Laboratories may implement an ISL TD as soon as it is approved by the WADA Executive Committee and published on WADA's website, provided that the requirements of the ISL TD have been implemented and documented in the Laboratory's Management System.]

c) Application of ISL *TDs*

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

[Comment to Article 1.1.2 c): For example, if the application of a newly approved ISL TD would result in an Adverse Analytical Finding (AAF) for a Sample with a collection date prior to the effective date of that new ISL TD, which would not have resulted in an AAF with the application of the version of the ISL 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 ISL 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 Test Report.]

ii. If the application of a newly approved ISL *TD* would lead to a result that benefits the *Athlete* [e.g., increase of the *DL* for a Threshold Substance or the *MRL* for a Non-Threshold Substance, establishment of more stringent identification criteria for qualitative chromatographic-mass spectrometric or electrophoretic Confirmation Procedure (CP)], then the new ISL *TD* shall be applied to the Analytical *Testing* of *Samples* as soon as it is approved by the *WADA* Executive Committee and published on *WADA*'s website (i.e., prior to the effective date). Therefore, in cases where an analytical finding does not meet the new reporting criteria, as defined in the new ISL *TD*, then the test result shall be reported as a Negative Finding. *WADA* shall instruct the Laboratories about such situations (for example, as part of the ISL *TD* Summary of Modifications).

iii. Subject to the above, the analysis of *Samples* and the review of Analytical Data, in compliance with the new ISL *TD*, may be implemented once an ISL *TD* has been approved, and the Laboratory has implemented and documented the requirements of the new ISL *TD* in their Management System.

1.1.3 ISL *Technical Letters*

ISL *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. ISL *TL*s are amended and/or withdrawn by *WADA* as appropriate.

a) Approval and Publication of ISL *TL*s

i. A stakeholder consultation (including Laboratories) shall be conducted for new ISL *TL* drafts.

ii. The stakeholder consultation may not be needed for a revised draft of an existing ISL *TL*, as determined by *WADA*. This may include when the implementation of the revised ISL *TL* is time sensitive (for example, to avoid detrimental *Consequences* on *Athletes*) or when low-impact editorial changes are needed (e.g., correction of typographical errors, formatting changes). Nevertheless, any such revisions of ISL *TLs* shall be reviewed and accepted by the Lab EAG before presentation of the new ISL *TL* version to the *WADA* Executive Committee for approval.

iii. Final versions of ISL *TL*s are approved by the *WADA* Executive Committee and published on *WADA*'*s* website.

b) Implementation of ISL *TL*s

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

ii. Approved ISL *TL*s become effective immediately, unless otherwise specified by *WADA*.

[Comment to Article 1.1.3 b): ISL TLs may require actions (e.g., validation of new Analytes or modifications to ATP(s), the procurement of Reference Materials – RMs – or Reference Collections – 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 ISL TL.]

iii. The implementation of the requirements of relevant ISL *TL*s into the Laboratory's Management System is mandatory for obtaining and maintaining *WADA* accreditation and for the application of the relevant ATP(s) to the analysis of *Samples.*

iv. If an approved ISL *TL* does not become effective immediately, as determined by *WADA*, the implementation of the requirements detailed in the approved and published ISL *TL* may occur prior to the effective date for implementation specified in the ISL *TL* and shall occur no later than that effective date (deadline for implementation).

v. A failure by a Laboratory to implement an ISL *TL* by the effective date may result in the imposition of an ATR against the Laboratory for that

ATP or for the analysis of that class of *Prohibited Substances* or *Prohibited Methods*, or a Suspension of the Laboratory's *WADA* accreditation, as determined by *WADA*.

c) Application of ISL *TLs*

i. When a newly approved version of an ISL *TL* lowers, for example, an *MRL* for a Non-Threshold Substance, the revised limits specified in the new ISL *TL* shall not be applied to the reporting of analytical results for *Samples* collected before the effective date of the ISL *TL* (if the ISL *TL* does not become effective immediately), even if the Laboratory already implemented and documented the requirements of the new ISL *TL* in their Management System before the effective date.

ii. If the application of a newly approved ISL *TL* would lead to a result that benefits the *Athlete* [e.g., increase of the *MRL* for a Non-Threshold Substance), then the new ISL *TL* shall be applied to the Analytical *Testing* of *Samples* as soon as it is approved by the *WADA* Executive Committee and published on *WADA*'s website (i.e., prior to the effective date, if not becoming effective immediately). Therefore, in cases where an analytical finding does not meet the new reporting criteria, as defined in the new ISL *TL*, then the test result shall be reported as a Negative Finding. *WADA* shall instruct the Laboratories about such situations (for example, as part of the ISL *TL* Summary of Modifications).

1.1.4 Laboratory Guidelines

Laboratory Guidelines (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 the relevant LGs.

1.1.5 Technical Notes

Technical Notes (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 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. The Laboratory may provide hard copies of TNs to representatives from ISO/IEC 17025 Accreditation Bodies (ABs), confidentially and upon request, for use during Laboratory AB Assessments.

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 determination of the exogenous origin, of Analyte(s) of *Prohibited Substance*(s) or *Prohibited Method*(s) in human biological fluids or tissues.

Laboratories may accept samples for other forms of analysis, subject to the provisions of the ISL Code of Ethics (see Article 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) and, therefore, shall not be subject to the requirements of the ISL, ISL *TD*s or ISL *TL*s. For the avoidance of doubt, Test Reports or other documentation or correspondence from Laboratories shall not declare or represent that any such testing is covered under their *WADA* accreditation 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 Annex A and Appendix 1).

a) Part Two of the ISL describes the requirements necessary to obtain and maintain *WADA* accreditation (Article 4.1) and *WADA* approval for the *ABP* (Article 4.2) and the procedures involved to fulfill these requirements, as well as the specific requirements to conduct Analytical *Testing* during Major *Events* (Article 4.3). It also includes the application of ISO/IEC 17025 [2] to the field of *Doping Control* (Article

[2] Effective version of ISO/IEC 17025.

5.0), a brief description of the *WADA* Laboratory monitoring and performance evaluation activities (Article 6.0) as well as the Laboratory disciplinary procedures (Article 7.0) and the ISL Code of Ethics (Article 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, as well as to facilitate the Assessment of Laboratory compliance by ABs 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, as well as the Appendix 1 (Definitions from the *Code* and other *International Standards* that are cited in the ISL, as well as ISL Definitions).

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, ABs are required to use the ISL, ISL *TD*s, ISL *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 External Quality Assessment Scheme (EQAS) and in routine Analytical *Testing*. The EQAS performance of Laboratories is continually monitored by *WADA* and reviewed as part of their AB Assessment process, as applicable. Therefore, the 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 2027 *Code* are directly relevant to the ISL; they can be obtained by referring to the *Code* itself:

- *Code* Article 2.1 Presence of a *Prohibited Substance* or its *Metabolites* or *Markers* in an *Athlete's Sample*
- *Code* Article 2.5 *Tampering* or *Attempted Tampering* with any Part of *Doping Control* by an *Athlete* or Other *Person*
- *Code* Article 4.5 *Monitoring Program*
- *Code* Article 6.2 Purpose of Analysis of *Samples* and Assessment of Analytical Data
- *Code* Article 6.3 Research on *Samples* and Data
- *Code* Article 6.4 Standards for *Sample* Analysis and Reporting
- *Code* Article 6.5 Additional Analysis of a *Sample* Prior to or During *Results Management*
- *Code* Article 6.6 Further Analysis of a *Sample* after it has been Reported as Negative or has Otherwise not Resulted in an Anti-Doping Rule Violation Charge
- *Code* Article 6.8 *WADA's* Right to Take Possession of *Samples* and Data

- *Code* Article 13.7 Appeals from Decisions Suspending or Revoking Laboratory Accreditation
- *Code* Article 14.3 Public Disclosure
- *Code* Article 19 Research
- *Code* Article 19.4 Research Practices
- *Code* Article 19.5 Research Using *Prohibited Substances* and *Prohibited Methods*

3.0 ISL *Technical Documents* and Interpretation

3.1 ISL *Technical Documents* cited in this version of the ISL[3]

i. ISL *TD* APMU – *Athlete* Passport Management Unit Requirements and Procedures.

ii. ISL *TD* ATP – Analytical *Testing* Procedures.

iii. ISL *TD* BSM – Analytical and Reporting Requirements for the Blood *Markers* of the Steroidal Module of the *Athlete Biological Passport*.

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

v. ISL *TD* DBS – Dried Blood Spots (DBS) for *Doping Control*. Requirements and Procedures for Analytical *Testing* and *Sample* Storage.

vi. ISL *TD DL* – *Decision Limits* for the Confirmatory Quantification of Exogenous Threshold Substances.

vii. ISL *TD* ENDO - Analytical and Reporting Requirements for the Blood *Markers* of the Endocrine Module of the *Athlete Biological Passport*.

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

ix. ISL *TD* EQAS – External Quality Assessment Scheme.

x. ISL *TD* GD – Detection of Gene Doping.

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

xii. ISL *TD* HBT - Detection of Homologous Blood Transfusion (HBT) by Flow Cytometry.

[3] Additional new ISL *TD*s may be drafted and published by *WADA,* which are not cited in this version of the ISL and, therefore, are not listed in this Article 3.1. Such new ISL *TD*s shall nevertheless be considered an integral part of the ISL and shall supersede any previous publication on a similar topic, including ISL *TL*s and/or the ISL.

xiii. ISL *TD* HEM – Analytical and Reporting Requirements for the *Markers* of the Hematological Module of the *Athlete Biological Passport*.

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

xv. ISL *TD* IRMS – Detection of Synthetic Forms of *Prohibited Substances* by GC/C/IRMS.

xvi. ISL *TD* LCOC – Laboratory Chain of Custody.

xvii. ISL *TD* LDOC – Laboratory Documentation Package.

xviii. ISL *TD MRL*: *Minimum Reporting Levels* applied in *Doping Control*.

xix. ISL *TD* MRPL – Minimum Required Performance Levels for Non-Threshold Substances.

xx. ISL *TD* NA: Harmonization of Analysis and Reporting of 19-Norsteroids

xxi. ISL *TD* PERF – Laboratory Performance Evaluation.

xxii. ISL *TD* USM – Analytical and Reporting Requirements for the Urinary *Markers* of the Steroidal Module of the *Athlete Biological Passport*.

xxiii. ISL *TD* VAL – Minimum Requirements for Validation of Analytical *Testing* Procedures for *Doping Control*.

3.2 Interpretation

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.

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.

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

Unless otherwise specified, references to Articles or Annex are references to Articles or the Annex of the ISL.

Where the term “days” is used in the ISL, it shall mean calendar days (i.e., all the days of the week including any non-working days) unless otherwise specified.

Terms used in this ISL that are defined terms from the *Code* are italicized. Terms that are defined in *International Standards* are underlined.

Defined terms from the *Code* and *International Standards* that are used in the ISL are found in Appendix 1.

The ISL *TD*s and ISL *TL*s have the same mandatory status as the rest of the ISL and constitute an integral part of it.

Annex A to the ISL has the same mandatory status as the rest of the *International Standard*.

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

- "Shall" to indicate a mandatory requirement.
- "Should" to indicate a recommendation.

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). The decision of the *WADA* Executive Committee shall be provided to the Applicant laboratory in writing.

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 advice on the initial 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).

A laboratory may only apply if its host country satisfies the following conditions:

a) It has a robust National Anti-Doping Program [in terms of Test Distribution Plan (TDP), *Sample* collection and *Results Management* activities] conducted by a *National Anti-Doping Organization* (*NADO*), which is compliant with the *Code* and the *International Standards* of the World Anti-Doping *Code*.

[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 their Sample collection activities were conducted in compliance with the International Standard for Testing (IST) and the IST TD on Sport Specific Analysis (IST TD SSA), as determined by WADA, and analyzed in a Laboratory(-ies).

By way of exception to this requirement, WADA may consider accepting an Applicant laboratory from a country where the application is supported by other ADOs in the region, which would guarantee a robust Regional Anti-Doping Program.]

b) It has ratified the UNESCO Convention against Doping in Sport, and

c) It has paid the annual financial contribution to *WADA*.

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

4.1.1.3 Provide 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 *Signatory*(-ies) [e.g., *NADO*(s) responsible for National Anti-Doping Program(s), International Federation(s) responsible for International Anti-Doping Program(s)] and/or *Delegated Third Party*(-ies) (*DTP*) in charge of *Sample* collection on behalf of *ADO*(s), collectively guaranteeing a minimum total number of 3,000 *Samples* (including urine, whole blood [4] and DBS *Samples*) annually, of which at least 2,500 shall be urine *Samples*.

[Comment to Article 4.1.1.3 b): To determine the minimum number of Samples, each Sample type (urine, whole blood, or DBS) 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 Provide Business Plan

The Applicant laboratory shall submit a business plan, upon request by *WADA,* which shall include market considerations (customers, number of *Samples*, maintenance costs, etc.), facility, instrumental, staffing and training plans, 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] Whole blood *Samples* may be venous or liquid capillary blood. Analysis can be performed on the whole blood or on the separated plasma or serum fraction obtained following *Sample* centrifugation. Whether serum or plasma is obtained depends on the tube used for the *Sample* collection (see also Article 5.3.3.2).

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 shall be forwarded to the *WADA* Executive Committee, which shall determine whether the laboratory shall 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. The decision of the *WADA* Executive Committee shall be provided to the Applicant laboratory in writing.

4.1.2.1 Payment of Initial 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 stages of the 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 4.1.2.7. This fee shall be determined by *WADA* and shall 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 shall include, but is not limited to, the following information:

a) Sources of laboratory funding (list of laboratory sponsors).

b) Staff list and their qualifications.

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

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

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

f) Status of ISO/IEC 17025 accreditation.

g) Status and details of their ATPs:

   i. Status of validated Initial *Testing* Procedures (ITPs) and Confirmation Procedures (CPs), including target Analytes and Limits of Detection (LODs), Limits of Identification (LOIs) and, where applicable, Limits of Quantification (LOQs) and Measurement Uncertainties (MUs).

ii. Status of method development and validation, including, at minimum, Validation Reports for all mandatory Analytical Methods (if completed) – see the ISL *TD* ATP.

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

h) 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.

i) A description of how the principles of the ISL Code of Ethics (see Article 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 provisions of the ISL Code of Ethics (see Article 8.0).

a) A Candidate laboratory shall not conduct any anti-doping Analytical *Testing* activities for *ADOs* 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 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 shall comply with the requirements of Laboratory independence and impartiality indicated in Article 4.1.4.2.5.

4.1.2.5 Establish a Mentoring Agreement

a) The Candidate laboratory shall establish agreement(s) (contract or Memorandum of Understanding) 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.

b) A Candidate laboratory shall obtain authorization from *WADA* to receive sensitive anti-doping information (e.g., methodological or

technological information, TNs or any other non-public information) and/or access to specific, *WADA*-developed anti-doping tests or materials (e.g., kits, RMs). *WADA* shall 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.

4.1.2.6 Analytical *Testing* Procedures of Candidate laboratory

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 ISL *TD*s and ISL *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.

4.1.2.7 Pre-Probationary Test 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 described in Articles 4.1.2.1 to 4.1.2.6, 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 ISL *TD* EQAS and the ISL *TD* PERF, respectively. 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* shall 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 Laboratory Documentation Package (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 AB 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, 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 shall 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.

4.1.2.8 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, or after any extension(s) to this period exceptionally approved by *WADA*, shall 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 shall be required to reapply for Candidate laboratory status as described in Article 4.1.1. *WADA* shall review each re-application on its own merits on a case-by-case basis and retains the right to reject repeated applications.

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 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 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 4.1.3.5. and 4.1.3.8. This fee shall be determined by *WADA*.

4.1.3.3 Compliance with the ISL Code of Ethics

The Probationary laboratory shall implement and comply with the provisions of the ISL Code of Ethics (see Article 8.0).

a) A Probationary laboratory shall not conduct any anti-doping Analytical *Testing* activities for *ADOs* 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.

4.1.3.4 Provide 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 R&D activities.

b) Official letter(s) of support from *Signatory*(-ies) [e.g., *NADO*(s) responsible for National Anti-Doping Program(s), International Federation(s) responsible for International Anti-Doping Program(s)] and/or *DTP*(s) in charge of *Sample* collection 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, whole blood [4] and DBS *Samples*) annually, 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 4.1.3.4 b): To determine the minimum number of Samples, each Sample type (urine, whole blood, or DBS) 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.

4.1.3.5 Analytical *Testing* Procedures of Probationary laboratory

a) Before entering the probationary phase, *WADA* shall inform the Candidate laboratory, in writing, of the minimum analytical requirements (Test Methods and target Analytes) that shall be validated, in compliance with the ISL and relevant ISL *TD*s and ISL *TL*s, for the laboratory to be able to participate in the EQAS during the probationary phase.

b) Prior to the scheduling of the FAT and On-site Assessment (see Article 4.3.1.8), the Probationary laboratory shall provide *WADA* with documentation to assess whether the required laboratory Analytical *Testing* capacity (refer to ISL *TD* ATP) has been reached.

4.1.3.6 Participate in the *WADA* External Quality Assessment Scheme

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 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 ATPs.

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

4.1.3.7 Obtain ISO/IEC 17025 Accreditation

The Probationary laboratory shall obtain ISO/IEC 17025 accreditation from an AB, with primary reference to the interpretation and application of the ISO/IEC 17025 requirements to the analysis of *Samples* (see Article 5.0) before the end of the probationary period (i.e., before *WADA* grants accreditation) and, if possible, before the FAT.

a) The AB shall be a full member of the Global Accreditation Cooperation Inc. and a signatory to the Mutual Recognition Arrangement (MRA) of the Global Accreditation Cooperation Inc. or, if not, it shall be full member of one of the approved and recognized Regional Accreditation Cooperation Bodies:

   - African Accreditation Cooperation (AFRAC).
   - Arab Accreditation Cooperation (ARAC).
   - Asia Pacific Accreditation Cooperation Inc. (APAC).
   - European co-operation for Accreditation (EA).
   - Inter American Accreditation Cooperation (IAAC).
   - Southern African Development Community Cooperation in Accreditation (SADCA).

b) The AB 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.

4.1.3.8 *WADA* Accreditation Assessment – Final Accreditation Test

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 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 4.1.3.12). At this stage, the Probationary laboratory is expected to have developed full capacity for the analysis of *Prohibited Substances* and *Prohibited Methods* as required from Laboratories (see ISL *TD* ATP). Therefore, compliance with the defined requirements for the application of ISO/IEC 17025 to the analysis of *Samples*, the ISL and other *WADA* Laboratory standards (ISL *TD*s, ISL *TL*s), and the practice and documentation of the laboratory, shall 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 ISL *TD* EQAS and the ISL *TD* PERF, respectively.

c) FAT EQAS reporting: The Probationary laboratory shall successfully report the results for the FAT EQAS samples 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 samples 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 AB may be invited as observers to the *WADA* On-Site Assessment.

f) FAT On-site Assessment evaluation: *WADA* shall provide a 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 before accreditation can be granted.

g) The Probationary laboratory's performance in the FAT EQAS and On-site Assessment shall 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 shall 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, Remote 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 4.1.3.12).

4.1.3.9 Plan and Implement Research and Development 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) anti-doping-related R&D activities (e.g., new research projects, Analytical Method development, drug administration studies) 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) Demonstrated willingness and ability to collaborate and share knowledge with Laboratories.

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.

4.1.3.10 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.

4.1.3.11 Obtain 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.

4.1.3.12 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) The decision of the *WADA* Executive Committee to revoke a Probationary laboratory status shall be provided to the Probationary laboratory in writing.

d) If a laboratory whose probationary status has been revoked wishes to continue its *WADA* accreditation process, it shall 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 *WADA* Accreditation

a) 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 4.1.3.11) have been satisfactorily met, the Lab EAG shall submit a recommendation that the laboratory be granted *WADA* accreditation to the *WADA* Executive Committee for approval.

b) The new Laboratory shall obtain a second opinion from another Laboratory(-ies) before reporting an *AAF* or *Atypical Finding* (*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

a) A *WADA* Accreditation Certificate 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.

b) A list of 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 shall 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 provisions of the ISL Code of Ethics (see Article 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* (Article 5.0), which is granted by an AB that is a full member of the Global Accreditation Cooperation Inc. and a signatory to the MRA of the Global Accreditation Cooperation Inc. or, if not, is full member of one of the approved and recognized Regional Cooperation Bodies (i.e., AFRAC, APAC, ARAC, EA, IAAC, SADCA).

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

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

   i. Under exceptional circumstances, and upon informing *WADA*, a Laboratory may apply a Test Method, which has been validated in conformity with ISO/IEC 17025 and ISL requirements, including its applicable ISL *TDs* and ISL *TLs*, to the analysis of *Samples* before its inclusion into the Laboratory's Scope of ISO/IEC 17025 Accreditation.

   [Comment to Article 4.1.4.2.4 b): For example, upon request by the Testing Authority (TA) (or Results Management Authority (RMA), if different), and after informing WADA, the Laboratory may apply a validated WADA-specific ITP that is not included in

its ISO/IEC 17025 Scope of Accreditation or for which analytical/reporting requirements have not been defined by WADA. The Laboratory shall retain any Samples producing a Presumptive Adverse Analytical Finding (PAAF) until the confirmation/reporting requirements have been established by WADA (in an ISL TD, ISL TL or LGs), after which the Laboratory, in consultation with the TA (or RMA, if different), may proceed to performing the validated CP and reporting the result in ADAMS accordingly.]

ii. In such cases, the Laboratory would not automatically benefit from the presumption that the Test Method is Fit-for-Purpose, as would otherwise be the case if the ATP 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 imply that the Laboratory is required to provide Test Method validation documentation or EQAS performance data in support of that *AAF*.

c) Flexible Scope of ISO/IEC 17025 Accreditation [5]

A Laboratory may modify or add Analytes to ATPs, which are included within its Scope of ISO/IEC 17025 Accreditation or develop new ATPs that involve technology already included within the Scope of ISO/IEC 17025 Accreditation, without the need for approval by the AB 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 AB that the Laboratory has 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 ATPs to detect new Prohibited Substances or Prohibited Methods, as well to 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:

[5] See the Global Accreditation Cooperation Inc. "TECH-1-007 Guidelines for Harmonization of Scopes of ISO/IEC 17025 Accreditation of WADA Anti-doping Laboratories" (previously known as the ILAC-G29/06:2020 Guidelines).

i. New ATPs

- Any ATP 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(-ies) or *WADA*-organized EQAS round(s) to evaluate whether the ATP is Fit-for-Purpose prior to providing formal approval.

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

ii. *WADA*-specific ATPs

- *WADA* shall require the Laboratory to seek an extension of their Scope of ISO/IEC 17025 Accreditation for *WADA*-specific ATPs 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.

- For more information on *WADA*-specific ATPs, refer to the ISL *TD* ATP.

4.1.4.2.5 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 *ADO,* 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 operate according to its own Management System and function without obstruction, interference, or manipulation from any *Person*. The Laboratory shall control, without limitation, the allocation of its budget, the acquisition of equipment and other resources, decisions regarding Laboratory personnel, R&D activities 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* External Quality Assessment Scheme

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

4.1.4.2.7 Provide 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 *Signatory*(-ies) and/or *DTP*(s) based on the

assessment of the Laboratory's annual *Testing* figures, or as otherwise determined by *WADA.*

4.1.4.2.8 Maintain Minimum Number of *Samples*

a) To maintain proficiency in Analytical *Testing*, the Laboratory is required to analyze a minimum of 3,000 *Samples* (including urine, whole blood [4] and DBS *Samples*), of which at least 2,500 shall be urine *Samples*, provided by *Signatory*(-ies) and/or *DTP*(s) in charge of *Sample* collection on behalf of *ADO*(s) annually.

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

b) *WADA* shall monitor the number of *Samples* tested by the Laboratory. If the total number of *Samples* analyzed for *Signatory*(-ies) and/or *DTP*(s) falls below 3,000 annually (or below 2,500 urine *Samples* annually), the Laboratory's *WADA* accreditation may be suspended (see Article 7.1.1).

c) 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* shall require that the Laboratory implement measures to maintain its proficiency in Analytical *Testing*, for example, by strengthening its internal Quality Assessment Scheme (iQAS) and Internal Audits (IA) program. *WADA* may also provide additional EQAS samples and/or conduct a Documentary Audit and/or an On-site or Remote Assessment, at its discretion and at the Laboratory's expense, to assess the status of the Laboratory's operations.

4.1.4.2.9 Implement Research and Development 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 programs 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): Research activities 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 new emerging or non-commercially available 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 (encrypted e-mail, or other written forms of *WADA*-approved secure communication, with confirmation of receipt, shall be accepted as a reporting mechanism).

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 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. The qualified *Person*(s) responsible for R&D activities (see Article 5.2.2.3).

ii. A sustainable R&D strategy and long-term plan, including objectives, planned deliverables, timelines and a knowledge dissemination scheme.

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 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 a 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 shall 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, further details or 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 points (see ISL *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 Publish Laboratory Analytical *Testing* Procedures and Services

The Laboratory shall report and maintain in *ADAMS* an up-to-date list of ATPs and services to assist *ADO*s in developing TDPs. Upon request by an *ADO*, the Laboratory should cooperate by providing other relevant information.

4.1.4.2.11 Participate in *WADA* / AB Assessments

a) AB Assessment during the Accreditation Cycle

i. The AB shall be a full member of the Global Accreditation Cooperation Inc. and a signatory to the MRA of the Global Accreditation Cooperation Inc. or, if not, it shall be a full member of one of the approved and recognized Regional Cooperation Bodies (i.e., AFRAC, APAC, ARAC, EA, IAAC, SADCA).

ii. The AB Assessment team shall include at least one ISL-trained assessor selected by the AB for the Assessment.

iii. The relevant AB should inform *WADA* of the anticipated Assessments and 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 AB's Assessment Report.

iv. 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 AB.

b) *WADA* Laboratory Assessment

WADA shall conduct On-site and/or Remote Assessments and/or Laboratory Document Audits as part of *WADA's* Regular Laboratory Monitoring Activities. The notice of a *WADA* Laboratory Assessment shall be made in writing to the Laboratory Director. In exceptional circumstances, and at *WADA*'s discretion, the Assessment may be unannounced (see also Article 6.1.2).

4.1.4.2.12 Issuing and Publication of Accreditation Certificate

a) On an annual basis, when maintenance of accreditation is approved, the Laboratory shall receive a *WADA* Accreditation Certificate. 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.

b) The list of Laboratories, and their contact information, is maintained on *WADA*'s website for stakeholder reference.

4.2 *WADA ABP* Laboratory Approval

The network of Laboratories may be geographically limited to serve the practical development of the Hematological Module of the *ABP*. Therefore, laboratories, which have the capability to analyze whole blood for the *Markers* of the Hematological Module of the *ABP*, may apply for *WADA ABP* approval 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). The decision of the *WADA* Executive Committee shall be provided to the Applicant *ABP* laboratory in writing.

[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 the Markers of the Hematological Module of the ABP in whole 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.

A laboratory may only apply if its host country satisfies the following conditions:

a) It has a robust National Anti-Doping Program (in terms of TDP, *ABP Sample* collection and *Results Management* activities) conducted by a *NADO*, which is compliant with the *Code* and the *International Standards* of the World Anti-Doping Program.

[Comment Article 4.2.1.2 a): 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 whole blood Sample collection activities for analysis of the Markers of the Hematological Module of the ABP were conducted in compliance with the IST (as determined by WADA) and analyzed in a Laboratory(-ies) or ABP Laboratory(-ies).

By way of exception to this requirement, WADA may consider accepting an Applicant ABP laboratory from a country where such application is supported by other ADOs in the region which would ensure a robust Regional ABP Program.]

b) It has ratified the UNESCO Convention against Doping in Sport, and

c) It has paid the annual financial contribution to *WADA*.

These conditions shall be documented as part of the application.

4.2.1.3 Provide 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 official letter(s) of support from *Signatory*(-ies) [e.g., *NADO*(s) responsible for National Anti-Doping Program(s), or International Federation(s) responsible for International Anti-Doping Program(s)] and/or *DTP*(s) in charge of *Sample* collection on behalf of *ADO*(s), collectively guaranteeing a minimum total number of 300 whole blood *Samples* for analysis of the *Markers* of the Hematological Module of the *ABP* annually. The letter(s) of support shall indicate:

a) The estimated number of whole blood *Samples* for analysis of the *Markers* of the Hematological Module of the *ABP* that will be provided to the *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*(-ies) that their relationship with the Applicant *ABP* laboratory is compliant with Article 4.1.4.2.5.

4.2.1.4 Provide Business Plan

The Applicant *ABP* laboratory shall submit a business plan, upon request by *WADA*, which shall include market considerations (customers, number of *Samples*, maintenance costs, etc.), facility, instrumental, staffing and training plans, 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, a recommendation shall be forwarded to the *WADA* Executive Committee to determine whether the Applicant *ABP* laboratory shall be granted *WADA* Candidate *ABP* laboratory status and thereby continue within the *WADA ABP* approval process. Additional supporting documentation may be requested by, and at the discretion of, the *WADA* Executive Committee. The decision of the *WADA* Executive Committee shall be provided to the Candidate *ABP* laboratory in writing.

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 shall include, but is not limited to, the following information:

a) Sources of laboratory funding (list of laboratory sponsors).

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

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

d) IT infrastructure and security: see Article 5.2.3.5.

e) List of actual and proposed instrumental resources and equipment for the *ABP*, including instrument maintenance plans and contracts.

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

g) Development and validation status of the Test Method for the analysis of the *Markers* of the Hematological Module of the *ABP*. Test Method Validation Report (if completed).

h) Status of laboratory's independence and impartiality as described in Article 4.1.4.2.5.

i) 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.

j) 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.

k) A description of the process to ensure that *ABP Samples* are processed and analyzed separately from clinical or other test samples, where applicable.

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

[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 provisions of the ISL Code of Ethics (see Article 8.0).

a) The Candidate *ABP* laboratory shall not conduct any anti-doping Analytical *Testing* activities for *ADOs* 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 Participate in the *WADA* External Quality Assessment Scheme for the Analysis of the *Markers* of the Hematological Module of the *ABP*

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 the *Markers* of the Hematological Module of the *ABP* with satisfactory performance (see ISL *TD* PERF). During this period, *WADA* may provide feedback to assist the Candidate *ABP* laboratory to improve the quality of its Analytical *Testing* process.

4.2.2.4 Independence and Impartiality

Before *WADA* grants *ABP* approval and to avoid potential conflicts of interest, the Candidate *ABP* 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 Obtain ISO/IEC 17025 or ISO 15189 Accreditation

The Candidate *ABP* laboratory shall obtain ISO/IEC 17025 or ISO 15189 accreditation for the analysis of the *Markers* of the Hematological Module of the *ABP* from an AB.

a) The AB shall be a full member of the Global Accreditation Cooperation Inc. and a signatory to the MRA of the Global Accreditation Cooperation Inc. or, if not, it shall be full member of one of the approved and recognized Regional Cooperation Bodies (i.e., AFRAC, APAC, ARAC, EA, IAAC, SADCA).

b) The AB Assessment team shall include at least one ISL-trained assessor selected by the AB 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 AB 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 *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 4.2.2.5.

[Comment to Article 4.2.2.6: The purpose of this On-site Assessment is to obtain information about different aspects of the Candidate laboratory's competence and verify compliance with the relevant ISL and ISL TD requirements (in particular, the ISL TD HEM).

At WADA's discretion, the On-site Assessment for the ABP approval may not be necessary or may be conducted online 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 before the end of the candidate *ABP* approval phase as per Article 4.2.2.8.

The Candidate *ABP* laboratory's performance in the *WADA* EQAS and On-site Assessment shall be considered in the overall review of

the laboratory's status and may affect the timeliness of the *WADA* approval.

4.2.2.7 Obtain 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.

4.2.2.8 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 shall submit a recommendation to the *WADA* Executive Committee to grant the laboratory the status of an *ABP* Laboratory.

4.2.3.2 Maintain *ABP* Laboratory Status

The *ABP* Laboratory shall meet the following requirements to maintain its *ABP* approval status:

a) Documented compliance with the ISL Code of Ethics (see Article 8.0).

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 in the analysis of the *Markers* of the Hematological Module of the *ABP*, as determined by *WADA*, in a *WADA* EQAS or similar *WADA*-approved Proficiency Testing program and during routine Analytical *Testing*.

f) Payment of fees related to the *WADA* EQAS or similar *WADA*-approved Proficiency Testing program for the analysis of the *Markers* of the Hematological Module of the *ABP*.

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 ATP(s) for the analysis of the *Markers* of the Hematological Module of the *ABP*, which are compliant with the ISL *TD* HEM.

i) Compliance with relevant *WADA* normative documents, including the ISL Article 5.0 and ISL *TD*s applicable to the analysis of whole blood *Samples* for the *Markers* of the Hematological Module of the *ABP* (e.g., ISL *TD* HEM, ISL *TD* LDOC, ISL *TD* LCOC).

j) Provision of Letter(s) of support from *Signatory*(-ies) and or *DTP*(s), if requested by *WADA*, as described in Article 4.2.1.3.

k) Analysis of the *Markers* of the Hematological Module of the *ABP* in a minimum of 300 whole blood *Samples* provided by *Signatory*(-ies) and/or *DTP*(s) in charge of *Sample* collection on behalf of *ADO*(s) annually.

l) Participation in *WADA* / AB Assessments (see Article 4.1.4.2.11).

m) Cooperation in support of the *Results Management* activities of *ADO*s.

4.2.3.3 Issuing and Publishing *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.

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*

a) 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.*

b) The Laboratory shall advise *WADA* when it becomes aware that they will be providing Analytical *Testing* services for a Major *Event*.

c) *Major Event Organizations* (*MEOs*) 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 to the Laboratory with minimal delay. This may require an existing Laboratory to establish a temporary "satellite facility" with appropriate capabilities for the Major *Event*.

d) In addition, an existing Laboratory's operational environment (e.g., facilities, analytical capabilities, staff) may not be adequate for the analytical and *Sample* processing capacity necessary for the Major *Event*. This may require the expansion of a Laboratory's existing facilities, the relocation 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.

e) There shall be a written agreement, at least three (3) months before the start of the Major *Event* (for Olympic and Paralympic Games, it is recommended that agreements are finalized at least six (6) months before the scheduled start of the Analytical *Testing*), between the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) and the Laboratory with respect to Analytical *Testing* requirements such as the TDP (including the expected number of urine, whole blood [4], and DBS *Samples* to be analyzed, the Analytical *Testing* menus to be applied, etc.) and test result turnaround times. The timing of the agreement shall consider the number of expected *Samples* and ATPs, and how they would impact the Laboratory's operational capabilities.

f) Upon *WADA*'s request, the Laboratory shall be responsible for providing *WADA* with regular and timely progress reports regarding its preparation for the Major *Event*.

4.3.1 Major *Event* Analytical *Testing* in the Laboratory Facilities

a) 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.

b) All new Test Methods required for the Major *Event* shall be validated at least two (2) months prior to the start of Analytical *Testing* for the Major *Event*, unless otherwise approved by *WADA*.

c) In addition, any changes to Test Methods, equipment or other procedures in the Management System shall 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 Participate in *WADA* Laboratory Assessment(s)

WADA may perform one or more Assessments (preferably on-site) of the Laboratory's existing facilities with the aim of evaluating the

Laboratory operations and the capability to provide Analytical *Testing* services for the Major *Event*.

a) The number and type of *WADA* Laboratory Assessments (On-site, Remote or Documentary Audit) shall 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 also include the analysis of EQAS samples.

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

c) A first *WADA* Assessment should be conducted no later than three (3) months before the scheduled start of the *Testing* for the Major *Event* (no later than six (6) months for Olympic and Paralympic Games). Emphasis shall be placed on the following:

   i. The latest version of the TDP provided by the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) 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 facilities to ensure that there is adequate analytical and *Sample* processing capacity (based on the expected number of *Samples* and requested 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, the analytical area(s), the *Sample* reception/processing room and the *Sample* storage units).

   [Comment to Article 4.3.1.1 c)-iv: If requested by the MEO and in accordance with applicable national laws or workplace regulations, a Laboratory 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 *Athlete*(s) attendance is kept confidential and protected from unsolicited external attention.

   vi. The Laboratory's IT security system, including restricted and secure central server(s), data management system [e.g.,

Laboratory Information Management System (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 ATP.

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

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

x. The capacity of the Laboratory's existing ATPs, including plans and timelines for method development and/or validation of any additional required ATP(s) two (2) months prior to the start of the *Testing* period for the Major *Event*.

xi. The Laboratory's Scope of ISO/IEC 17025 Accreditation, including timelines for 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 iQAS and IA 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 its performance of the Major *Event* 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*. The stress test(s) shall be conducted no later than two (2) months before the start of the *Testing* period for the Major *Event*.

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

d) *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 at the Laboratory's expense, before the scheduled start of *Testing* for the Major *Event.*

e) The final *WADA* Laboratory Assessment should be conducted no later than one (1) month before the start of *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 infrastructure 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, unless otherwise approved by *WADA*.

   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* Laboratory Assessment(s) have been satisfactorily addressed.

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

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

g) An Assessment Report shall be issued to the Laboratory and the Lab EAG within thirty (30) days of 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 *Testing* for the Major *Event*.

h) *WADA* shall inform the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*), and notify the Laboratory when doing so, of any identified Major Nonconformity (NC) which represents a serious risk in the Laboratory's ability to conduct the required Analytical *Testing* menu for the Major *Event* (e.g., if the Laboratory will not be ready to perform a specific ATP, or any other serious procedural or logistical deviations that cannot

be resolved before the start of *Testing* for the Major *Event*), so that the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) can implement adequate alternatives [for example, the subcontracting of the affected ATP(s) to another Laboratory(-ies)].

4.3.1.2 Participate in the *WADA* External Quality Assessment Scheme

a) At its sole discretion, *WADA* may submit (blind and/or double-blind) EQAS samples to the Laboratory in preparation for or during a Major *Event*. The EQAS samples shall be analyzed using the same ATPs that will be applied in the analysis of *Samples* for the Major *Event*.

   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 the disqualification of the Laboratory from performing the Analytical *Testing* for the Major *Event*.

b) In addition, the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) may also request *WADA* to submit double-blind EQAS samples for Laboratory analysis while performing Analytical *Testing* during a Major *Event*. The request to *WADA* for the preparation of the double-blind EQAS samples shall be made no later than three (3) months before the start of *Testing* for the Major *Event*. The *MEO* shall be responsible for providing the necessary resources and covering the costs associated with the preparation, characterization, shipment and introduction of the double-blind EQAS samples into the TDP for the Major *Event*.

4.3.1.3 Pre-*Event* Report

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

a) A valid signed contract between the Laboratory and the responsible *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) including a TDP detailing the *Sample* collection schedule, number of *Samples* (including urine, whole blood [4], and DBS *Samples*, as applicable) and requests for specific analyses [e.g., Erythropoietin Receptor Agonists (ERAs)].

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 contribution).

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. In addition to Analytical *Testing* requirements, emphasis should be given to the ISL Code of Ethics (see Article 8.0) 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.

f) A list of ATPs 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 Obtain 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 Standard Operating Procedure (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 5.3.4.1.4 e), a representative from *WADA* or *WADA*'s *Independent Observer Program* team (if requested by *WADA* or the 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* (or *DTP* delegated to undertake *Results Management* responsibilities for the Major

Event), and considering that a 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* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) shall clarify the reporting timelines for Negative Findings, *AAF*s, *ATF*s and the reporting of specific test results (e.g., GC/C/IRMS, ERAs) as well as the *Therapeutic Use Exemption* enquiry process [see Article 5.3.4.1.3 c)] and additional analysis requests (e.g., as indicated by *Athlete* Passport Management Unit (APMUs) – see also ISL *TD* APMU).

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 Participate in *WADA* Laboratory Assessment(s)

WADA may perform an initial Assessment of the "satellite facility", at the Laboratory's expense, 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 shall 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 is 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* Laboratory Assessments in preparation for a Major *Event* refer to Article 4.3.1.1.

4.3.2.2 Document ISO/IEC 17025 Accreditation of the "Satellite Facility"

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

4.3.2.3 Obtain 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 Obtain 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 WADA Assessment.

c) Based on the documentation provided, *WADA* reserves the right to decide regarding the 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 *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) 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

Article 5.0 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 ISL *TD*s, ISL *TL*s or LGs shall be governed by ISO/IEC 17025 (or ISO 15189, as applicable for *ABP* Laboratories).

Article 5.0 focuses on the specific parts of the Laboratory's 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) Resource Requirements.

b) Process Requirements.

c) Management Requirements.

5.2 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 applicable mandatory normative documents (ISL *TD*s, ISL *TL*s).

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, Laboratory Chain of Custody (LCOC) protocols, and the SOPs for the ATPs performed.

Specific criteria shall be met by the Laboratory Director, Laboratory Quality Management Staff, Laboratory Responsible(s) for R&D Activities (or qualified *Person*) 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 appointed on a full-time basis. If the Laboratory Director has other duties or does not work full-time in the Laboratory, these shall not adversely affect the performance of the Laboratory Director's inherent activities and associated 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); or
      - In the absence of a postgraduate degree, a Bachelor degree in one of the natural or life sciences with a minimum of ten (10) years' experience in a senior laboratory position.

   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 [e.g., at a level similar to level B2 of the European Framework of Reference for Languages (CEFR)].

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 their position. A succession plan shall be forwarded to *WADA*. *WADA* reserves the right to review the credentials of such an 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.

c) 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.

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

i. A higher education degree (for example, 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 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 Responsible(s) for Research and Development Activities

The Laboratory shall have a qualified *Person*(s) responsible for R&D activities. The qualifications should include:

a) A doctoral degree (Ph.D. or equivalent) in one of the natural or life sciences, or a Master degree with a documented ability to oversee research projects and a minimum of ten (10) years' experience in R&D relevant to anti-doping (e.g., from the fields of forensic toxicology, analytical chemistry or biomedical sciences).

b) Ability to plan and execute research projects, with a demonstrated capability to write scientific articles, posters, perform oral communications and share knowledge.

c) Knowledge of *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.

5.2.2.4 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 (QC) results, LDOCs and Certificates of Analysis (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. A higher education degree (for example, 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. Advanced knowledge of relevant ISL *TD*s, ISL *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 administrative, *Sample* processing, *Sample* storage and analytical areas, which comply with the security requirements outlined below:

a) The Laboratory shall perform a risk assessment and have a policy for the security of its facilities, equipment, and systems against unauthorized access.

b) Two (2) main levels of access shall be defined in the Management System and evaluated in the risk 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.
- Where necessary, the Laboratory shall require authorized external 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 systems 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 members. 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 (where applicable). 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* [6] 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 AB (evidence of continued accreditation and/or acceptance of suitability of the new Laboratory facilities required when made available by the AB).

d) New Laboratory contact information and coordinates.

e) Assessment of the effect of the Laboratory relocation on customer 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 the use of controlled chemicals and reagents, waste disposal procedures, electrical services, environmental health and safety policies, etc.

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 Uninterruptible Power Supply (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 equipment failure.

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[6] This refers to *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 ATPs).

5.2.3.4 Maintain 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 whole blood/DBS *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 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 by using adequate security measures.

c) The Laboratory shall implement a software-based data and information management system with secure and restricted access to stored electronic data by authorized personnel only, which supports and maintains proper traceability of Laboratory operations and facilitates information and data exchange capabilities between the Laboratory and *ADAMS* (e.g., LIMS).

[Comment to Article 5.2.3.5 c): The data and information management system may also feature process workflow management, Sample and Aliquot LCOC, control of stocks of RMs, 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 (2) 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 (e.g., a commercial LIMS), 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 ATPs 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

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 or authorized for use by *WADA*.

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

5.2.5.1 Reference Materials

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 an RM is not a Certified Reference Material (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 RMs or RCs), 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 an 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 Quantitative Procedures applied for the confirmation of Threshold Substances.]

5.2.5.2 Reference Collections

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

a) An external QC sample.

b) An Aliquot or extract from a urine, whole blood or DBS sample obtained after controlled administration conducted in accordance with the requirements established in Article 8.2.1.

c) 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.

[Comment to Article 5.2.6 a): Subcontracting the analysis for the Markers of the Hematological Module of the ABP to another Laboratory or ABP Laboratory is not a recommended practice due to the limited time requirements for such analysis – see also ISL TD HEM.]

b) 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 Analytical Method 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(s) and CP(s), if needed). However, for the "B" *Sample* analysis, 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* 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. However, the responsibility for the validity of the analytical results and any *Results Management* support requests lies with the subcontracted Laboratory that performed the relevant analysis.

ix. When the request for external analysis is due to a Laboratory's inability to apply a mandatory ATP (see ISL *TD* ATP), without informing the TA in advance of this lack of analytical capacity (temporary or not), the Laboratory making the request for external analysis shall bear the costs of *Sample* transportation to the subcontracted Laboratory(-ies) as well as any additional analytical costs.

c) 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 ISL *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 *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* (including DBS *Samples* that are transferred to long-term storage without being analyzed) shall be inspected and irregularities, if identified, recorded (see Article 5.3.2.1). However, analyzed *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* with Laboratory internal *Sample* codes, which provide *Sample* traceability to the collection document or other external chain of custody information.

5.3.2 Acceptance of *Samples* for Analysis

Except as provided in Article 5.3.2 d), urine or blood *Samples* from a *Signatory* (or *DTP*) 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 ATP.

The Laboratory shall analyze each *Sample* received from a *Signatory* (or *DTP*), 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 (SCS) 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 ATP(s). In such cases, the analytical result obtained for the combined Sample shall be reported independently for each Sample collected, while clarifying in the Test Reports that the result was obtained after the analysis of the combined Samples.]

b) In cases where the Laboratory receives three (3) or more urine *Samples*, which are linked to a single SCS from the same *Athlete* according to the DCF(s), the Laboratory shall prioritize the analysis of the first and the subsequent collected *Sample* with the highest specific gravity (SG), as recorded in the DCF:

[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 ATP(s). In such cases, the analytical result obtained for the combined Sample shall be reported independently for each Sample analyzed, while clarifying in the Test Reports that the result was obtained after the analysis of the combined Sample.

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 *Samples* during the same SCS, provided that the following process is followed:

i. The TA shall request, in advance and in writing, the Laboratory to place the DBS *Samples* directly into storage (without an initial analysis).

ii. The Laboratory shall report the DBS *Sample* as Not Analyzed in *ADAMS* (see Article 5.3.6.4.1) and transfer the *Sample* to storage under appropriate conditions (preferably frozen). The TA shall be responsible for the costs associated with the registration, initial storage and reporting of the DBS *Samples* by the Laboratory.

iii. The TA shall inform the Laboratory in writing, within six (6) months following DBS *Sample* reception, if the *Sample* shall be put in long-term storage, or if it shall be analyzed (in which case the TA shall inform the Laboratory of the Analytical *Testing* menu to be applied). The TA shall be responsible for any costs associated with an extended DBS *Sample* storage beyond six (6) months (see also Table 1 in Article 5.3.7 and the ISL *TD* DBS).

iv. If the *Sample* is analyzed following the instructions of the TA, the Laboratory shall update the *ADAMS Sample* record accordingly.

v. If no request is received from the TA for the long-term storage or analysis of the DBS *Sample* within six (6) months following *Sample* reception, the Laboratory may discard the *Sample* or use it for secondary purposes (in accordance with Article 5.3.8).

5.3.2.1 *Samples* with Irregularities

a) The Laboratory shall observe and document as part of the *Sample*'s records, 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 ATPs (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 5.3.7.2).

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

[Comment to Article 5.3.2.1 b). The irregularities marked with an asterisk (*) in this Article 5.3.2.1 b) may not impact on the Sample's chain of custody/unique identification or the suitability of the Sample to be analyzed with the requested test menu.]

i. Inadequate *Sample* transportation conditions, for example:

- *Samples* found to have been exposed to high temperatures (e.g., for *Sample* packages containing temperature data loggers) *.
- Issues with temperature logger, e.g., not working, not started, has stopped, or is absent (when applicable) *.
- Missing "A" or "B" *Samples*.
- The "A" or "B" *Sample* is broken, empty, damaged or leaking.

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 (unless this difference is traceable to the DCF).
- *Sample* identification numbers are different between the "A" and the "B" *Sample* containers of the same *Sample* (unless this difference is traceable to the DCF).
- *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.

iii. Unusual *Sample* conditions, for example:

- Color, odor, presence of turbidity or foam in a urine *Sample* *.
- Color, signs of hemolysis in a whole-blood *Sample* *.
- Freezing or clotting of a whole blood *Sample*.
- Unusual differences in *Sample* appearance (e.g., color and/or turbidity) between the "A" and the "B" *Samples* (see ISL *TL*14) *.
- The *Sample* matrix is incompatible with the test menu requested (e.g., whole blood *Samples* to be analyzed for the *Markers* of the Hematological Module of the *ABP* collected in serum tubes instead of EDTA tubes).
- *Sample* volume does not meet the criteria for Suitable Volume of Urine for Analysis or is otherwise inadequate to perform the requested Analytical *Testing* menu.
- The Laboratory cannot open the *Sample* container (for example, for containers requiring specific opening tools).
- *Tampering* or adulteration of the *Sample* is evident.
- *Sample* is not properly sealed with *Tampering*-evident device.

c) Analysis of *Samples* with Irregularities

i. The Laboratory may analyze *Samples* with irregularities if the irregularity does not impact on the *Sample*'s chain of custody/unique identification or the suitability of the *Sample* to be analyzed with the requested test menu (as marked with an asterisk (*) in Article 5.3.2.1 b) above). In any case, those irregularities shall be noted in the Test Report in *ADAMS*.

ii. Considering the time constraints for the analysis of the *Markers* of the Hematological Module of the *ABP*, it is recommended that the Laboratory proceeds with the analysis of the whole blood *Sample*(s) with irregularities, unless the

analysis is not possible or the irregularity(-ies) may adversely impact the analytical equipment (e.g., blood clots that may cause clogging of the instrument's capillary components). The Laboratory shall report the noted irregularity(-ies) in *ADAMS*.

iii. For the irregularities of *Samples* (other than whole blood *Samples* collected for the analysis of the *Markers* of the Hematological Module of the *ABP*) that affect the *Sample*'s chain of custody/unique identification or its analytical suitability (without an asterisk (*) in the list of examples listed in Article 5.3.2.1 b) above), the Laboratory shall seek instructions from the TA, in writing, on the performance of Analytical *Testing* on the *Sample* (unless there is a prior agreement between the Laboratory and the TA to analyze such *Samples*):

- The TA shall inform the Laboratory, in writing within seven (7) days, whether a *Sample* with the 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.
- In the absence of a timely reply (within seven (7) days) by the TA, the Laboratory should report the *Sample* as "Not Analyzed" in *ADAMS*. However, the Laboratory may, at its discretion, analyze the *Sample* (for example, if *Sample* substitution is suspected).
- In cases where the TA (or the RMA, if different) or *WADA* requests the *Sample* analysis after the Laboratory had reported it as Not Analyzed in *ADAMS*, this shall be considered a Further Analysis (see Article 5.3.4.2).

iv. Whether a *Sample* with noted irregularities is analyzed or not (following or not the receipt of TA instructions), the Laboratory shall report in *ADAMS*:

- Any noted irregularities, and
- The TA instructions authorizing or not the *Sample* analysis, or
- A comment clarifying that the TA did not reply to the Laboratory's request for instructions on the performance of Analytical *Testing* on a *Sample* with irregularity(-ies), and therefore the *Sample* was not analyzed (when applicable).

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*'s integrity has been compromised.

   When the integrity of the "A" or "B" *Sample* container is compromised (e.g., improper sealing or broken seal, or if the Laboratory mistakenly opens the "B" *Sample* instead of the "A" *Sample*) and there are no clear signs of *Sample Tampering*, the Laboratory shall notify and seek authorization from the TA to perform the ITP(s) on the affected *Sample* ("A" or "B", as applicable).

   - If the ITP(s) of the affected *Sample* ("A" or "B", as applicable) produces a PAAF(s), the Laboratory shall proceed to the splitting procedure (in accordance with the provisions of this Article 5.3.2.2) of the complementary, sealed *Sample* ("B" or "A", respectively) to conduct Analytical *Testing*, including the repeat of the ITP analysis and the performance of the relevant CP(s).
   - However, if the initial ITP(s) on the affected *Sample* ("A" or "B", as applicable) produces negative results, the Laboratory shall report the finding as a Negative Finding.
   - If the TA does not authorize the performance of the analysis on the affected *Sample* ("A" or "B", as applicable), the Laboratory shall inform *WADA* about the TA's decision in writing.

   iii. Upon visual inspection, the *Sample* is suspected of being heavily contaminated (see also ISL *TL*14).

   iv. 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:

   i. If the TA decides to not 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.

ii. If the TA does not respond to the Laboratory's request for a *Sample* splitting procedure in a timely manner (within seven (7) days), the Laboratory shall report the *Sample* as "Not Analyzed" in *ADAMS* and include a comment clarifying that the TA did not reply to the Laboratory's request for authorization to perform the *Sample* splitting procedure.

iii. In cases where the TA (or *WADA*) requests the *Sample* splitting and analysis after the Laboratory had reported it as Not Analyzed in A*DAMS*, this shall be considered a Further Analysis (see Article 5.3.4.2).

c) The process of opening and splitting the *Sample* and resealing of the remaining second fraction shall be conducted in accordance with Article 5.3.4.1.4 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 shall occur at a specified date and time and advise the *Athlete* of the opportunity to observe the process in person and/or through a representative.

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

ii. If the *Athlete* cannot be located, does not respond or the *Athlete* and/or their 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.

iii. Even if present during the splitting procedure, the *Athlete* and/or their representative(s) has no right to attend the ATP(s) to be performed on the first split fraction, which is considered as the "A" *Sample*.

d) The first fraction of the split *Sample* shall be considered as the "A" *Sample* and shall be used for the ITP(s), unless the ITP(s) have already been performed (for example, on an "A" *Sample* with insufficient volume), and/or the "A" CP(s), if necessary. The second fraction, considered as the "B" *Sample*, shall be resealed, and stored frozen for "B" CP(s), if necessary.

e) When the splitting procedure concerns whole blood *Samples*, which have been collected for Analytical *Testing* on the serum/plasma fraction, the sealed, intact ("A" or "B") whole blood *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 above.

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 ITPs or CPs shall minimize the risk of contamination of the *Sample* or the 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.

d) Urine "A" *Samples* should be frozen after Aliquots are taken for the ITP(s) to minimize the risk of *Sample* microbial degradation [7].

e) Urine "B" *Samples* shall be stored frozen, as soon as possible, after reception until analysis [7].

[7] Unless otherwise established in an ISL *TD* or ISL *TL*.

5.3.3.2 Whole Blood *Samples*

a) Whole blood can be collected as venous blood [8] or liquid capillary blood [9].

b) The Laboratory shall follow the mandatory requirements of relevant ISL *TD*s and ISL *TL*s for processing and storing whole blood *Samples*. Recommendations of best-practice provided in LGs should also be considered.

c) The Laboratory shall obtain Aliquot(s) from the whole blood *Sample* container by using single-use disposable pipettes or pipettes with disposable, non-reusable tips [10].

i. *Samples* for which Analytical *Testing* shall be performed on the whole blood or on its cellular fraction [11].

- Whole blood *Samples* shall be maintained refrigerated as much as practicable and shall be analyzed according to established protocols.
- After Aliquots have been taken for analysis, if applicable, *Samples* shall be returned to refrigerated storage as soon as practicable. Whole blood *Samples* shall not be frozen.
- If additional analyses are to be performed on the plasma fraction of the whole blood *Sample*, then:
  - For the analysis of the *Markers* of the Hematological Module of the *ABP*, the *ABP* analysis shall be completed before any other analysis is performed on the *Sample*.
  - For whole blood *Samples* collected for analyses other than the *Markers* of the Hematological Module of the *ABP,* the Laboratory may complete the analyses (including the ITP(s), and any applicable “A” and/or “B” CP) on the whole blood before centrifuging the *Sample* to obtain the plasma fraction for the additional analyses (e.g., ERAs), or

    The whole blood *Sample* may be split into two (2) or more Aliquots to be used for the performance of analyses in whole blood (e.g., HBT) and for analyses in the plasma fraction following centrifugation (e.g., ERAs).

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[8] Whole venous blood *Samples* are collected by venipuncture.

[9] Whole capillary blood *Samples* are collected from capillary blood vessels through puncture/incision of the skin.

[10] Except for the analysis of the *Markers* of the Hematological Module of the *ABP*.

[11] Analysis in whole blood means that the blood *Sample* is used for analysis as such, without separation (by centrifugation or other means) into the blood cellular and liquid fractions. However, the analysis may target specifically either the blood cells [e.g., for the *Markers* of the Hematological Module of the *ABP* and homologous blood transfusions (HBT)] or the whole blood fraction (e.g., gene doping, DNA analysis).

ii. Whole blood *Sample*s for which Analytical *Testing* shall be performed on blood liquid fraction (serum or plasma) only (not on cellular components) [12].

- Whole blood *Samples* ("A" and "B" *Samples*), for which Analytical *Testing* shall be performed on the plasma/serum fraction only shall be centrifuged, as soon as practical, after Laboratory reception to obtain the plasma or serum fraction[13].
- 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 ISL *TD*, ISL *TL* or LGs) or frozen until analysis.
- "A" *Sample* serum or plasma Aliquots used for "A" CPs should be analyzed as soon as possible, but no later than twenty-four (24) hours after thawing [13].
- 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 (RBCs) lysed upon thawing, until analysis (if applicable) [13].
- Following the conclusion by the Laboratory of a PAAF in the "A" *Sample*, the Laboratory shall transfer the corresponding "B" *Sample* tube to storage at -70 °C or less [13].
- "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 [13].

5.3.3.3 Dried Blood Spot (DBS*) Samples* [14]

DBS *Sample* storage and aliquoting shall follow the directives from the ISL *TD* DBS, or other applicable ISL *TD* or ISL *TL*. Recommendations of best practice provided in LGs should also be considered.

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[12] For obtaining serum, whole blood shall be collected in serum tubes which contain a gel separator and clotting activator. For plasma, whole blood shall be collected in tubes containing an anti-coagulant (EDTA). Analyses in serum include but are not limited to tests for human Growth Hormone (hGH), the blood *Markers* of the Endocrine and Steroidal Modules of the *ABP*, steroid esters, insulins, ERAs and Hemoglobin-based Oxygen Carriers (HBOCs). Analyses in plasma include but are not limited to tests for ERAs, steroid esters, insulins and HBOCs.

[13] Unless otherwise specified in an ISL *TD* or ISL *TL*.

[14] To obtain DBS *Samples*, capillary blood is collected directly on an absorbent *Sample* support and allowed to dry. DBS *Samples* are collected in accordance with *IST* Annex J - Collection, Storage and Transport of DBS *Samples*.

5.3.4 Analysis of *Samples*

a) The Laboratory shall apply only validated, Fit-for-Purpose ATPs 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 *In-Competition* (*IC*) or *Out-of-Competition* (*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 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 ADO 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*, *Markers* of urine *Sample* substitution or *Tampering*), if applicable.

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

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

Results from these additional analyses listed in this Article 5.3.4 c) shall be reported in *ADAMS* if specifically required by *WADA* (for example, see *Code* Article 4.5 for reporting results of the *Monitoring Program*, or the ISL *TD* USM for reporting confounding factors affecting the measurement of the urinary *Markers* of the Steroidal Module of the *ABP*) or in the Comments field of *ADAMS* for TA/RMA information purposes.

d) At minimum, the Laboratory is required to implement all mandatory ATPs, as determined by *WADA* in specific ISL *TD*s or ISL *TL*s (see also ISL *TD* ATP). The Laboratory may implement additional methods for the analysis of particular *Prohibited Substances* or *Prohibited Methods*.

[Comment to Article 5.3.4 d): Mandatory ATPs are those Analytical Methods for which the Laboratory shall have available analytical capacity, in compliance with relevant ISL TDs or ISL TLs, 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 ATP 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 documentation provided to the Laboratory. WADA shall maintain the list of mandatory ATPs in the ISL TD ATP.]

e) ATP(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 ATP 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, the ISL *TD* VAL and/or other applicable ISL *TD*s or ISL *TL*s 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 also Article 4.1.4.2.4).

f) Laboratories may, on their own initiative and prior to reporting a test result, apply additional ATP(s) to analyze *Samples* for Prohibited *Substances* or *Prohibited Methods* not included in the requested *IC* or *OOC* test 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 RMA, if different) or *WADA*, to Further Analysis (see also *Code* Article 6.4.1). Results from any such analysis shall be reported in *ADAMS* and have the same validity and *Consequences* as any other analytical result.

5.3.4.1 Selection and Validation of Analytical *Testing* Procedures

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

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

c) Affinity-binding assays (e.g., Immunoassays), electrophoretic and flow cytometric methods and other Analytical Methods are 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 ITP and CP shall 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 5.3.4.1 c)- iv: 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 RBCs using flow cytometry. The flow cytometer is set up to selectively recognize RBCs. The presence of more than one surface Marker on the RBCs (as determined by antibody labelling) may be used as a criterion for an AAF (alternatively to using multiple antibodies of the same Marker).]

d) Validation results for ATPs shall be summarized in a Validation Report and supported by the necessary documentation and Analytical Data.

For more details on ATP validation requirements, refer to the ISL *TD* VAL.

5.3.4.1.1 Initial *Testing* Procedures

a) The objective of the ITP is to obtain information about the potential presence of Analyte(s) of *Prohibited Substance*(s) or *Prohibited Method*(s).

b) Results from ITPs that are Quantitative Procedures can be included as part of *Athlete* Passports (e.g., *Markers* of Hematological, Steroidal or Endocrine Modules of the *ABP*), provided that the method is Fit-for-Purpose.

c) The ITPs shall fulfill the following requirements:

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

[Comment to Article 5.3.4.1.1 c)-i: In cases when the "A" Sample cannot be used for the ITP, the ITP 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 QC samples prepared in the matrix of analysis, in accordance with its method validation results (see ISL *TD* VAL) [15].

iv. The Laboratory shall establish criteria, based on its Test Method validation results, to evaluate results from an ITP as a PAAF, which would trigger confirmation analyses.

v. Results from ITPs are not required to consider the associated MU [15].

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

5.3.4.1.2 Confirmation Procedures

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 Test 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 Test Method's validation results or as specifically required by the TA (or RMA, if different) or *WADA* [15].

d) The CPs shall fulfill 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. The CP should incorporate, if possible and appropriate, additional target Analyte(s) of the

[15] Unless otherwise specified in an ISL *TD* or ISL *TL*.

Prohibited Substance(s) or *Prohibited Method*(s).

iii. CPs that are Quantitative Procedures shall provide accurate quantification results, including an acceptable MU as established in relevant ISL *TD*s or ISL *TL*s.

iv. Incorporate, if possible and adequate, a different *Sample* extraction protocol and/or a different analytical methodology [15].

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

5.3.4.1.3 "A" Confirmation Procedure

a) Aliquots

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

[Comment to Article 5.3.4.1.3 a)-i: 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).]

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.

b) Target Analyte(s)

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

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

– Existence or not of an approved *Therapeutic Use Exemption*, as confirmed

by the TA (or RMA, if different) 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 analysis (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 *Therapeutic Use Exemption*

i. The Laboratory may contact the TA (or RMA, if different), in writing, to enquire whether an approved *Therapeutic Use Exemption* exists (for further guidance, refer to the LGs on *Therapeutic Use Exemption* enquiries) when there is a PAAF for the following *Prohibited Substances*, before proceeding to the "A" CP:

- Amfetamine.
- Beta-blockers.
- Beta-2 Agonists.
- Clomifene (for female *Athletes*).
- Diuretics.
- Glucocorticoids.
- hCG.
- hGH (Biomarkers Test).

- Methylphenidate.
- Narcotics.
- Tamoxifen (for female *Athletes*) and
- Any other *Prohibited Substance* or *Prohibited Method* for which the *Athlete* declared *Use* in the DCF.

[Comment 1 to Article 5.3.4.1.3 c)-i: The selection of substances for Therapeutic Use Exemption enquiries above is based on criteria such as prevalence of medical use (upon Therapeutic Use Exemption approval) 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 Therapeutic Use Exemption 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 shall assume the additional costs for the shipment of the Sample to the subcontracted Laboratory.]

[Comment 2 to Article 5.3.4.1.3 c)-i: In principle, the enquiry by Laboratories regarding the existence of an approved Therapeutic Use Exemption 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 Therapeutic Use Exemption for the Use of a prohibited route of administration or a dose exceeding the maximum allowed inhalation dose established in the Prohibited List.]

ii. When possible, the Laboratory should provide an estimated concentration of the Analyte(s) from 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 *Therapeutic Use Exemption,* shall be provided to the Laboratory in writing (for further guidance, refer to the LGs on *Therapeutic Use Exemption* 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 CP upon confirmation of the existence of an approved *Therapeutic Use Exemption* by the TA (or RMA, if different):

- The Laboratory shall report the finding as a Negative Finding in *ADAMS* and include a comment in the Test Report that the PAAF was not confirmed upon verification by the TA (or RMA, if different) of the existence of an approved *Therapeutic Use Exemption*.
- The TA (or RMA, if different) shall provide *WADA* with the associated *Therapeutic Use Exemption* number recorded in *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.

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

[Comment to Article 5.3.4.1.3 d)-iv: 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

The "A" CP of a Non-Threshold Substance (whether subject to *MRL* or not) shall be based on the application of a Qualitative Procedure to establish the presence (in compliance with the ISL *TD* IDCR and/or other relevant ISL *TD* or ISL *TL*) of Analyte(s) of the Non-Threshold Substance in the "A" *Sample*.

In addition, for the "A" CP of a Non-Threshold Substance with *MRL*, the Laboratory shall follow the requirements established in applicable ISL *TDs* (e.g., ISL *TD MRL*) or ISL *TLs* to estimate whether the concentration of the relevant Analyte(s) of the Non-Threshold Substance is higher than the *MRL.*

f) "A" CP for Threshold Substances

i. The "A" CP of a Threshold Substance shall be based on the application of the following procedures:

- A chromatographic-mass spectrometric Qualitative Procedure (where applicable) for the identification (in compliance with the ISL *TD* IDCR) of relevant Analyte(s) of the Threshold Substance (as established in the ISL *TD DL* or other relevant ISL *TD* or ISL *TL*), and
- A Quantitative Procedure to determine if the property value (e.g., concentration, ratio, score, or any other measurable analytical variable, as defined by *WADA*) of relevant Analyte(s) of the Threshold Substance (as established in the ISL *TD DL* or other relevant ISL *TD* or ISL *TL*) in the "A" *Sample* exceeds the value of the corresponding *DL*, which is specified in the ISL *TD DL* or other applicable ISL *TD* (e.g. ISL *TD* GH, ISL *TD* CG/LH) or ISL *TL*.

  By determining that the test result exceeds the *DL*, the quantitative CP establishes that the Analyte(s) of the Threshold Substance is present in the *Sample* at a level greater than the Threshold, with a statistical confidence of

at least 95% (for more information, refer to the ISL *TD DL*).

The quantitative CP for a Threshold Substance shall be based on the determination of the mean of measured property values in three (3) "A" *Sample* Aliquots [16]. If there is not enough *Sample* volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

ii. For endogenous Threshold Substances, *Markers* of the *ABP*, or any other *Prohibited Substance* that may be produced endogenously, the "A" CP may also be based on the application of any Fit-for-Purpose Test Method that establishes the origin (exogenous or endogenous) of Analyte(s) of the Threshold Substance in accordance with a relevant ISL *TD* (e.g., ISL *TD* IRMS, ISL *TD* NA) or ISL *TL*.

5.3.4.1.4 "B" Confirmation Procedure

a) 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.

b) Notification of "B" CP

i. The Laboratory shall only perform the "B" CP upon written request from the relevant *ADO* with *Results Management* responsibilities.

ii. The responsible RMA should, if possible, inform the Laboratory in writing, within thirty (30) days following the reporting of an "A" *Sample AAF* by the Laboratory, whether the "B" CP is to be conducted.

[Comment to Article 5.3.4.1.4 b)-ii: The "B" CP should be conducted as promptly as possible, in particular for the

[16] Unless otherwise specified in an ISL *TD* or ISL *TL*.

confirmation of Analytes that may degrade during Sample storage (e.g., ERAs, Markers of HBT).]

iii. If the Laboratory does not receive instructions from the responsible RMA on the conduct of the "B" CP or the transfer of the "B" *Sample* to long-term storage within the minimum applicable *Sample* storage time (see Article 5.3.7.1 and Table 1), then the Laboratory shall transfer the "A" and "B" *Samples* into long-term storage and inform *WADA*. The *ADO* shall bear the costs for the extended *Sample* storage.

c) Timing of "B" CP

i. It is recommended that, if requested, the "B" CP is performed as soon as possible (e.g., within thirty (30) days, if possible) of reporting the *AAF* for the "A" *Sample*.

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). In such cases, if the *Athlete* or the *Athlete's* representative cannot be present, the procedure shall then be conducted in the presence of an Independent Witness.

ii. The responsible RMA shall instruct the Laboratory to proceed with the "B" CP, in the presence of an Independent Witness, if:

- The *Athlete* declines to be present in person and/or through a representative, or
- The *Athlete* will not attend (in person and/or through a representative) once a date and time for the analysis have been fixed, 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 *ADO* responsible, 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 process:

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.
- Upon request and subject to the approval by the Laboratory Director (or designated *Person*), the *Athlete* and/or one (1) representative may also have reasonable opportunity to observe other steps of the "B" CP process, as long as they strictly follow the instructions of the Laboratory and do not interfere with the analytical process and the Laboratory's routine operations, including respecting the Laboratory's operational hours as well as the Laboratory's safety and security requirements. Any questions on the analytical process shall be directed exclusively at the Laboratory Director (or designated *Person*).

  The observation by the *Athlete* and/or their representative of the "B" CP process shall

not involve the interpretation of the Analytical Data, which is a sole responsibility of the Laboratory. The *Athlete* shall receive all necessary Analytical Data, and their interpretation and conclusions made by the Laboratory, in the LDOC (upon request through the RMA or *WADA*).

ii. An Independent Witness.

iii. A translator (if applicable).

iv. A representative of the responsible *ADO* (if requested by the *ADO*).

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 process:

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(s), if they are not following the Laboratory 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 responsible *ADO*.

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

[Comment to Article 5.3.4.1.4 g)-i: 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" CP(s), 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 their 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* 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 process and shall inform the responsible *ADO* immediately to obtain instructions. In such cases, the "B" CP may have to be rescheduled.
- 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 process. In addition, the Laboratory shall inform the *ADO* responsible 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(s) are taken in the presence of the *Athlete* or their representative(s) or the Independent Witness.

v. The Laboratory shall also ensure that, after opening and taking Aliquots for the "B" CP(s), the "B" *Sample* is properly resealed in the presence of the *Athlete* and/or their 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 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 reason(s) 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 process.

h) Target Analyte(s)

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

i. The order of priority of the confirmation(s) shall be determined to prioritize the analysis of the *Prohibited Substance*(s) or *Prohibited Method*(s) with the longest potential period of *Ineligibility*.

ii. The decision should be made in consultation with the *ADO* responsible and documented in writing.

i) Repetition of the "B" CP(s)

i. The Laboratory may repeat the "B" CP, if appropriate (e.g., QC failure, chromatographic peak interferences, inconclusive "B" confirmation results). When the CP is repeated, the reasons that led to the 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 resealed "B" *Sample* container. In such cases, the reopening, aliquoting and resealing 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.

[Comment to Article 5.3.4.1.4 j)-i: 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, as long as the Analyte(s) targeted allows the unequivocal and conclusive identification of the Prohibited Substance or Prohibited Method in the "B" Sample to conclude an AAF.

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

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

iii. The Laboratory shall conduct an internal investigation of the cause(s) of the discrepancy between the "A" and "B" *Sample* results and should report its outcomes to the RMA and *WADA* within seven (7) days.

k) "B" CP for Non-Threshold Substances and Exogenous Threshold Substances

i. The "B" CP for a Non-Threshold Substance (including those with *MRL* as specified in the ISL *TD MRL*) or an exogenous Threshold Substance includes a Qualitative Procedure, which shall only confirm the presence (in compliance with the ISL *TD* IDCR or other applicable ISL *TD* or ISL *TL*) of Analyte(s) of the *Prohibited Substance* reported in the "A" *Sample* for the *AAF* to be valid.

ii. Quantification or estimation of concentrations of the Analyte(s) of the *Prohibited Substance* in the "B" *Sample* is not necessary.

l) "B" CP for Endogenous Threshold Substances

For an endogenous Threshold Substance, the "B" CP shall be based on:

i. A Quantitative Procedure to determine if the property value (e.g., concentration, ratio, score, or any other measurable analytical variable, as defined by *WADA*) of relevant Analyte(s) of the Threshold Substance (as established in relevant ISL *TD* or ISL *TL*) in the "B" *Sample* exceeds the value of the applicable *DL* [17], which is specified in a relevant ISL *TD* (e.g., ISL *TD* GH, ISL *TD* CG/LH) or ISL *TL*.

- 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.
- The quantitative "B" CP for an endogenous Threshold Substance shall be based on the determination of the mean of measured property values (e.g., concentration, ratio,

[17] 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*.

score, or any other measurable analytical parameter, as defined by *WADA*) of three (3) "B" *Sample* Aliquots [18].

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

ii. A chromatographic-mass spectrometric Qualitative Procedure (if applicable) for the identification (in compliance with the ISL *TD* IDCR) of relevant Analyte(s) of the Threshold Substance (as established in relevant ISL *TD* or ISL *TL*).

iii. For endogenous Threshold Substances, Markers of the *ABP*, or any other *Prohibited Substance* that may be produced endogenously, the "B" CP may also be based on the application of any Fit-for-Purpose Test Method that establishes the origin (exogenous or endogenous) of Analyte(s) of the Threshold Substance in accordance with a relevant ISL *TD* (e.g., ISL *TD* IRMS, ISL *TD* NA) or ISL *TL*.

5.3.4.2 Further Analysis

Further Analysis of a stored *Sample* shall, as a matter of principle, be aimed at detecting *Prohibited Substances* or *Prohibited Methods* included in the *Prohibited List* in force at the time of the collection of the *Sample.*

a) Requests for Further Analysis

i. Requests for Further Analysis shall be made by the TA or RMA (if different) in writing and shall be recorded as part of the *Sample*'s documentation.

ii. *WADA* may also direct the additional analysis (see *Code* Article 6.5) or Further Analysis (see *Code* Article 6.6) of *Samples* at its own expense. In cases where *WADA* takes physical possession of a *Sample*(s), it shall notify the TA (see *Code* Article 6.8).

iii. Any other *ADO* with jurisdiction that wishes to conduct Further Analysis on a stored *Sample* may do so upon request with the permission of the TA or *WADA* and shall be responsible for any follow-up *Results Management.*

[18] Unless otherwise specified in an ISL *TD* or ISL *TL*.

b) Selection of *Samples* for Further Analysis

i. Further Analysis on a *Sample* before the reporting of analytical results

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*.

However, if a Laboratory is to conduct additional analysis on an "A" *Sample* or "B" *Sample* after a final report (see Article 5.3.6.4 for partial submission of results) for that *Sample* has been issued (for example: additional *Sample* analysis to detect ERAs, or GC/C/IRMS analysis, or analysis in connection with the *ABP* or additional analysis on a stored *Sample*), this shall be considered as Further Analysis. Therefore, the Laboratory shall get approval from the TA or RMA (if different) or *WADA*, as applicable.

ii. Further Analysis of a *Sample* Reported as a Negative Finding

There is no limitation for the conduct of Further Analysis on a *Sample* that has been reported as a Negative Finding.

iii. Further Analysis of a *Sample* Reported as *AAF*

- Further Analysis may be performed on a stored *Sample* reported as an *AAF* if the responsible *ADO* has not notified the *Athlete* that the *Sample* is the basis for a *Code* Article 2.1 Anti-doping Rule Violation charge, or after that case has been finally resolved. Any *Prohibited Substance* or *Prohibited Method* detected during the Further Analysis, which was prohibited at the time of *Sample* collection, shall be reported.
- Pursuant to *Code* Article 6.5, Further Analysis may not be applied on a *Sample* reported as an *AAF* 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.
- However, 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 provided that the analytical result from that Further Analysis cannot be used against the *Athlete* (for example, reanalysis 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) – see also Article 6.1.3.

iv. Further Analysis of a *Sample* Reported as *ATF*

Further Analysis may be performed on a *Sample* reported as an *ATF* except if, following additional investigations, the finding has been progressed into an *AAF* and the *Athlete* has been charged with a *Code* Article 2.1 Anti-doping Rule Violation (for example, findings for some *Prohibited Substances* that may be used as growth promoters for livestock in some countries, which are initially reported as *ATF* and later progressed as *AAF* after further investigations establish that the result cannot be explained by the consumption of contaminated meat).

v. Previously acquired ITP data may also be re-evaluated for the presence of *Prohibited Substances* or *Prohibited Methods*, at the initiative of the TA (or the RMA, if different), *WADA* or the Laboratory at its own discretion. The results of such re-evaluation, if suspicious, shall be communicated to the TA, the RMA (if different) or *WADA*, as applicable, and may lead to Further Analysis.

c) Selection of Laboratory for Further Analysis

Further Analysis may be performed by the same Laboratory that performed the original Analytical T*esting*, or by a different Laboratory or other *WADA*-approved laboratory, at the direction of the TA (or RMA, if different) or *WADA*.

d) ATPs for Further Analysis

i. Further Analysis of stored *Samples* shall be performed in compliance with the ISL, ISL *TD*s and ISL *TL*s 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 ATP(s) and/or the analysis of new target Analyte(s) 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 ATP(s)].

e) Further Analysis of Stored *Samples*

i. Use of the "A" *Sample*

- The TA or RMA (if different) or *WADA* may instruct the Laboratory to use the "A" *Sample* for:
  - Both the ITPs(s) and the "A" CP(s); or
  - Only the ITP(s); or
  - Not to use the "A" *Sample* for Further Analysis at all.

- If the Laboratory has been instructed to perform only ITP(s) on the "A" *Sample*, any suspicious analytical result obtained from the "A" *Sample* shall be considered as a PAAF, irrespective of the ATP applied, and shall be confirmed using the split "B" *Sample* (see below).

ii. Use of the split "B" *Sample*

- When the "A" *Sample* is used only for the ITP(s) or is not used at all during Further Analysis, the "B" *Sample* shall be split and used for Further 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* shall 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 their representative has no right to attend the ATP(s) 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 5.3.4.1.4.

[Comment to Article 5.3.4.2 e)-ii: 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 ITP(s) and "A" CP(s) or "A" CP(s) only (if the ITP(s) was already performed using the "A" Sample).]

5.3.4.3 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 Assurance* schemes, which are appropriate to the type and frequency of Analytical *Testing* performed by the Laboratory.

i. The *Quality Assurance* 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 Assurance* procedures shall be documented in the Laboratory Management System.

b) The range of *Quality Assurance* activities include, but are not limited to:

i. Use and monitoring appropriate QC samples.

- Appropriate positive (PQC) and negative (NQC) samples, prepared in the matrix of analysis, shall be included, and analyzed in all ITPs and CPs [19].
- Appropriate internal standard(s) shall be used for chromatographic methods.
- QC-charts with appropriate warning and action limits shall be used to monitor method performance and inter-batch variability (where applicable).

ii. Implementation of an Internal Quality Assessment Scheme

- The Laboratory shall establish a functional and robust risk assessment-based iQAS program, which challenges the entire scope of the Analytical *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 samples on a regular basis (e.g., monthly); and
  - 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

[19] Unless otherwise specified in an ISL *TD* or ISL *TL*.

- The management of the iQAS results (reviewing and follow-up of nonconformities).

iii. Mandatory participation in the *WADA* EQAS (see ISL *TD* EQAS).

iv. Implementation of Internal Audit Program

– IAs 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 IAs, 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 Management and Reporting of Analytical Results

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 ISL *TD*s (e.g., ISL *TD* EPO) or ISL *TL*s, required by *WADA* from certain Laboratory(-ies) for all or for specific ATP(s) 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. If not a member of the relevant *WADA* Technical Working Group, the second opinion provider shall be at least a Certifying Scientist for the ATP and shall be approved to provide second opinions by their 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 respect 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 [20].

d) Laboratory Review of Results before Reporting *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. ITP and CP Analytical Data and calculations.

iv. QC data.

v. Completeness of technical and analytical documentation supporting the reported findings.

vi. 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)-vi: 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

[20] Unless otherwise specified in an ISL *TD*, ISL *TL* or LGs.

to non-prohibited substances or the absence of characteristic phase-I or phase-II Metabolites.]

vii. 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 (or RMA, if different) or *WADA* to a Laboratory shall be made in writing.

f) LDOCs and CoAs shall be compliant with the ISL *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 ISL *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, *DTP*, *WADA,* other parties informed including, where different, National Federations, International Federations, *National Olympic Committees* (*NOCs*).

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 e-mails 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 RMA (see also Article 5.3.4.2).

b) Unless specifically requested (or previously agreed with the TA, RMA, or *WADA*) to make a partial submission of test results [21], a Laboratory should 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* 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, pursuant to *Code* Article 6.5, 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 performed 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., CP(s) for atypical or suspicious *Markers* of the *ABP*, ERA analysis for a suspicious hematological Passport), which are triggered by *ADAMS* notifications or APMU requests (see ISL *TD* APMU) after the "A" *Sample* has already been reported as an *AAF*, then the Laboratory shall advise the RMA that if the *Athlete* has been charged with a *Code* Article 2.1 Anti-doping Rule Violation, pursuant to *Code* Article 6.5 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.

[21] A partial submission of Test Results may occur for *Results Management* purposes, for example, when the availability of analytical results is time-sensitive (e.g., during Major *Events*) and other ongoing analyses may take longer to complete before the result is reported (for example, due to limited analytical capacity, longer times of *Sample* processing and analysis, ongoing relevant investigations, or the need to obtain second opinions pursuant to ISL Article 5.3.6.1.c).

c) Reporting Timelines

i. Reporting of "A" *Sample* results by Laboratories should occur in *ADAMS* within twenty (20) days of receipt of the *Sample*, unless any of the following conditions apply:

- GC/C/IRMS analysis has been requested by the TA as part of the initial Analytical *Testing* menu. In those cases, the "A" *Sample* results should be reported in *ADAMS* within twenty-five (25) days of *Sample* receipt.
- The Laboratory has a prior agreement with the TA(s) regarding extended reporting times beyond twenty (20) days or has informed the TA (or RMA, if different) in *ADAMS* of any delay in the reporting of "A" *Sample* results, including the applicable reason(s), and the TA (or RMA, if different) has agreed to an extension of the reporting deadline. In the absence of feedback from the TA (or RMA, if different) within seven (7) days of being notified by the Laboratory of the extended reporting deadline and its reason(s), the Laboratory should proceed with the assumption that the extended reporting deadline has been accepted by the TA (or RMA, if different).

  To the extent possible, any agreed extension to the "A" *Sample* reporting deadline should not surpass forty-five (45) days from the data of reception of the *Sample* by the Laboratory.

  [Comment to Article 5.3.6.4 c). Valid reasons for an extension of the results reporting timelines include, but are not limited to, the need to obtain second opinion(s) before the result can be reported (e.g., for ERA results – see ISL TD EPO); the need to subcontract an analysis that is not within the Laboratory's Scope of ISO/IEC 17025 Accreditation; a pending additional analysis that requires more time to complete (for example, if it depends on the collection of a follow-up Sample); the need for the splitting of the "A" or "B" sample (see Article 5.3.3.2); a temporary Laboratory analytical incapacity (e.g., instrument breakdown or need for Test Method revalidation), a failure by the TA to answer to Laboratory's enquiries in a timely manner, or national statutory holidays. If an extension to the reporting timelines is not approved by the TA, then the Laboratory, in consultation with the TA, shall subcontract the analysis to another Laboratory.]

ii. 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 *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*). In such cases, an agreement may be made with the Laboratory to prioritize the analysis of the Major *Event Samples* over other *Samples*. Requests by the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*) for quicker

reporting timelines shall be made (in writing) and agreed with the Laboratory and managed in *ADAMS*.

- Where a *Sample* is collected from an *Athlete* within twenty (20) days prior to the *Athlete's* first competition at an Olympic or Paralympic Games for which an *Athlete* has qualified or is likely to participate, upon request of the TA and pursuant to the agreement with the Laboratory, the relevant *Sample*(s) should be prioritized by the Laboratory for expedited analysis. Results shall be reported, at the latest, seventy-two (72) hours prior to the *Athlete's* first *Competition* or (where applicable and possible) prior to the opening ceremony of the Olympic or Paralympic Games (see also *IST* Article 4.8.3).
- Where a Laboratory is unable to meet the TA's request for prioritized analysis, it shall inform the TA as soon as possible so that the TA can contact an alternative Laboratory(-ies) to have the *Samples* prioritized for analysis. Any costs associated with the additional shipment of the *Samples* to an alternative Laboratory are the responsibility of the TA.
- When the analysis of Major *Event Samples* is prioritized, the Laboratory shall inform their other customers, so that they can agree to a possible delayed analysis of their *Samples* or decide to send the *Samples* to another Laboratory(-ies).

iii. The reporting of results for the *Markers* of the Hematological Module of the *ABP* by Laboratories should occur in *ADAMS* within three (3) days of receipt of the *Sample* (see ISL *TD* HEM).

iv. Delays in reporting shall not invalidate a test result (including *AAFs* or *ATFs*).

v. 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 requesting *ADO.*

vi. *WADA* shall monitor Laboratory reporting times on a regular basis (e.g.*,* quarterly). If a Laboratory's reporting delays are considered extensive [e.g.*,* more than 30% of *Samples* are not reported within recommended period without a valid reason, as determined by *WADA* - see also Comment to Article 5.3.6.4 c)], the Laboratory shall be requested to provide a Corrective Action Report (CAR) to remedy the situation, which shall be evaluated by the Lab EAG. If the delays in reporting are not resolved to the satisfaction of the Lab EAG, then the

Laboratory shall be assigned points as per the Points Scale Table (see ISL *TD* PERF).

5.3.6.4.1 Reporting Requirements

a) The Laboratory shall record the test result for each individual *Sample* from *ADOs* 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 ISL *TD*s or ISL *TL*s, and in the ISO/IEC 17025 standard, the following:

i. The SG of the urine *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 or RMA, if different (for example, for *Target Testing* of the *Athlete*).

iv. Specific tests performed in addition to the Laboratory's routine Analytical *Testing* menu (e.g., ERAs, GC/C/IRMS, hGH, HBT, DNA, genomic profiling, etc.).

v. Any irregularities noted on *Samples*.

vi. Any refusal by the *Athlete* and/or their representative(s) or the Independent Witness, as applicable, to sign the Laboratory documentation for the "B" *Sample* opening, aliquoting or resealing procedures (see Article 5.3.4.1.4).

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*. However, upon request by the *ADO*, the Laboratory may report additional information directly to the *ADO* after reporting the test

results in *ADAMS* (for example, estimated concentrations of Non-Threshold Substances).

d) *WADA* may also request the Laboratory to report additional analytical data (e.g., reference population data) in a format specified by *WADA*. In addition, the Laboratory shall also provide any information requested by *WADA* in relation to the *Monitoring Program* (see *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

iv. Not Analyzed

[Comment to Article 5.3.6.4.1 e)-iv: The Laboratory shall report as "Not Analyzed" any Sample received at the Laboratory which is not subjected to Analytical Testing for a valid, documented reason (as instructed by or agreed with the TA) such as Sample irregularities, intermediate Samples of a SCS, etc. (see Articles 5.3.2 and 5.3.2.1).]

5.3.6.4.2 Test Report for Non-Threshold Substances

a) "A" *Sample* Test Report

Following the Laboratory's report of the "A" *Sample* results as an *AAF* or an *ATF* for a Non-Threshold Substance, the RMA or *WADA* may request (in writing), and the Laboratory shall provide (where possible), the estimated concentration(s) of the Analyte(s) of the Non-Threshold Substance detected in the *Sample*, irrespective of whether the Non-Threshold Substance is subject to an *MRL* or not.

The Laboratory shall report the estimated concentration in writing (and include in the LDOC, if requested) and indicate that the concentration was estimated by a Qualitative Procedure that has not been validated for quantitative purposes.

[Comment to Article 5.3.6.4.2 a) The Laboratory may, occasionally, be unable to report the estimated concentration of the Analyte(s) for a Non-Threshold Substance not subject to an MRL (for example, in the absence of corresponding RM(s), when the identification

of the Analyte(s) has been based on the use of a RC(s) for which the concentration of the Analyte(s) is not known)].

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 ISL *TD* IDCR or other applicable ISL *TD* or ISL *TL*) as an *AAF.*

  [Comment to Article 5.3.6.4.2 a)-i: When applicable, the Laboratory shall record in the ADAMS Test Report the specific Analyte(s) of the Non-Threshold Substance that were identified in the Sample.]

- The Minimum Required Performance Level (MRPL) is not a reporting requirement for a Non-Threshold Substance without an *MRL* (see also the ISL *TD* MRPL). Therefore, the Laboratory should report the presence of a Non-Threshold Substance without an *MRL* at an estimated concentration below the MRPL (or below the validated LOI – see *TD* VAL) if an Analyte of the Non-Threshold Substance is identified in the "A" *Sample* in accordance with the ISL *TD* IDCR and/or other applicable ISL *TD* or ISL *TL.*

ii. Non-Threshold Substances subject to an *MRL*

- The Laboratory shall report the Non-Threshold Substance as an *AAF* when the relevant target Analyte(s) [22] identified in the "A" *Sample* (in accordance with the ISL *TD* IDCR or other applicable ISL *TD* or ISL *TL*) are present at an estimated concentration which is higher than the corresponding *MRL* (see ISL *TD MRL*).

- Under certain circumstances, the Laboratory may report the presence of a Non-Threshold Substance with an *MRL* if identified in a *Sample* at an estimated concentration below the *MRL*, in accordance with the ISL *TD MRL*.

[22] The relevant target Analyte(s) of a Non-Threshold Substance subject to an *MRL* is the 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 a relevant ISL *TD* (e.g., ISL *TD MRL*) or ISL *TL*.

[Comment to Article 5.3.6.4.2 a)-ii: For avoidance of doubt, nothing shall prevent the Laboratory, upon written request by the TA (or RMA, if different) or WADA, from disclosing to the requesting ADO information about the presence of a Non-Threshold Substance with an MRL at an estimated concentration below the MRL.]

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* present (i.e., identified), at any level, in the "B" *Sample* (in accordance with the identification requirements established in the ISL *TD* IDCR or other applicable ISL *TD* or ISL *TL*). The Laboratory is not required to estimate nor report the concentration of the Non-Threshold Substance in the "B" *Sample*.

[Comment to Article 5.3.6.4.2 b): Where applicable, the Laboratory shall record in the ADAMS Test Report the specific Analyte(s) of the Non-Threshold Substance that were identified in the "B" Sample.]

5.3.6.4.3 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 Analyte(s) of the *Prohibited Substance* is present at a level of a measured property value (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) greater than the *DL*, and/or that the Analyte(s) of the *Prohibited Substance* is of exogenous origin.

ii. Where the value of an Analyte(s) of a Threshold Substance exceeds the Threshold value but is less than or equal to (≤) the *DL*, the Laboratory shall report this result as a Negative Finding and include a recommendation (e.g., in the comments section of the Test Report in *ADAMS*) for the *ADO* (TA or RMA, if different, or *WADA*) to consider this result for *Target Testing* purposes.

[Comment to Article 5.3.6.4.3 a)-iii: For avoidance of doubt, nothing shall prevent the Laboratory, upon written request by the TA (or RMA, if different) or WADA, from disclosing to the requesting ADO information about the presence of a Threshold Substance at a concentration below the DL.]

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 Analyte(s) of the *Prohibited Substance* (in accordance with the ISL *TD* IDCR or other applicable ISL *TD* or ISL *TL*). 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 ISL TD IDCR or other applicable ISL *TD* or ISL *TL*) Analyte(s) of the *Prohibited Substance* is present at a level of a measured property value (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*), which is greater than the *DL* [23], or
- The Analyte(s) of the *Prohibited* Substance is of exogenous origin.

[23] 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*.

5.3.7 Storage of *Samples* [24]

5.3.7.1 Minimum Storage of *Samples*

a) The Laboratory shall store *Samples* in a restricted and secure location under appropriate storage conditions and continuous LCOC.

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, at minimum, for the applicable storage periods defined in Table 1 below after reporting all *Sample* results ("A" and "B", as 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).

   i. 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 (see Table 1) following the reporting of the "A*" Sample* analytical result.

   ii. However, if the "B" *Sample* CP is performed, then the Laboratory shall retain both the "A" and "B" *Samples* for the corresponding minimum storage time after reporting the "B" *Sample* analytical result.

d) Unless there is a prior agreement in writing with the Laboratory, the RMA or *WADA* is responsible for requesting the Laboratory to extend the *Sample* storage period (including those *Samples* reported as *AAFs* or *ATFs*), beyond the applicable minimum *Sample* storage time defined in Table 1. Requests for long-term storage to the Laboratory and confirmation by the Laboratory that the *Sample*(s) have been placed into long-term storage shall be made in *ADAMS*.

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.

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

Table 1. Minimum *Sample* Storage Periods

Sample Matrix		Storage conditions [a]	Minimum Storage times [b]		
			Negative Finding	Not Analyzed	*AAF / ATF* [c]
Urine		Frozen (≤ -15°C)	3 months	3 months	6 months
Whole Blood	Whole venous or liquid capillary blood [d]	Refrigerated	1 month	1 month	3 months
	Plasma [e]	Frozen (≤ -15°C)	3 months	3 months	6 months
	Serum [e]				
DBS [f]		Frozen (≤ -15°C)	6 months	6 months [g]	

[a] Or as otherwise established in an ISL *TD* or ISL *TL*.

[b] 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 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* shall require the approval of the TA (or RMA, if different) or *WADA*.

[c] 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" *Samples* for the corresponding minimum storage time after reporting the "B" *Sample* analytical result.

[d] *Samples* for which Analytical *Testing* was performed on the whole blood or on its cellular fraction, including those collected for the analysis of the *Markers* of the Hematological Module of the *ABP*.

[e] 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 storage at -70 °C or less. After the "B" *Sample* is opened for CP aliquoting, the resealed "B" *Sample* shall be returned to storage at -70°C or less.

[f] If the Analytical *Testing* has been performed on the cellular fraction of a DBS *Sample*, then the minimum storage periods established for whole blood *Samples* shall be followed.

[g] Not Analyzed DBS *Samples* shall be stored, at a minimum, for the storage period requested by the TA. The TA shall be responsible for any costs associated with an extended DBS *Sample* storage period beyond six (6) months.

5.3.7.2 Long-term Storage of *Samples*

At the direction of the TA (or RMA, if different) 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 5.3.7.1) for up to ten (10) years after the *Sample* collection date for the purpose of Further Analysis (see Article 5.3.4.2). Any extended *Sample* storage initiated by an *ADO* shall be conducted at the *ADO*'s expense.

[Comment to Article 5.3.7.2: For the transfer of ownership of Samples after the applicable minimum required storage periods or when placed under long-term storage to another ADO with jurisdiction over the Sample, refer to IST Articles 10.2.3 to 10.2.5).]

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 LCOC.

ii. The written request from the TA (or RMA, if different) 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, 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 (which is not part of the Laboratory's accredited area), and if the *Sample(s)* are not within the immediate supervision of a Laboratory staff member throughout the transfer, the Laboratory shall secure the "A" *Sample(s)* to be shipped either by resealing the 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 LCOC. Neither the *Athlete* nor their representative nor an Independent Witness is required to be present for this procedure.

[Comment to Article 5.3.7.2 a)-iii: For example, Sample(s) may be resealed with new resealing systems (e.g., new bottle caps) 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 resealing 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 their representative or by an appointed Independent Witness.
- During transport and long-term storage, *Sample(s)* shall be stored at an appropriate temperature 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 Analytes of *Prohibited Substances* or *Prohibited Methods* (e.g.*,* full-scan mass spectrometry data) as detailed in Article 5.3.4.2 b)-v.

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) *ADO* 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 *ADO* that has ownership over the *Samples*, or under the responsibility of a *DTP* designated by the *ADO* for the storage of the *Samples* (while the *ADO* retains ownership of 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 *ADO*/*DTP* shall ensure that *Samples* are stored according to established protocols in a secure location under continuous chain of custody.
   - The *ADO*'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 *Sample*'s external chain of custody and other non-analytical records to the *ADO*, 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 5.3.7.1), and neither the TA (or RMA, if different) 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 *Athlete* (see also *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 the 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)-iii: If the Laboratory is unsure whether a study can proceed without Athlete consent after consulting the foregoing sources, the Laboratory shall consult 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* or Aliquot or related data to another party.

5.3.9 Complaints [25]

The Laboratory shall handle complaints in accordance with ISO/IEC 17025.

5.3.10 Control of Nonconformities in Analytical *Testing* [25]

The Laboratory shall have policies and procedures that shall be implemented when any aspect of its Analytical *Testing* does not comply with the 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 Root Cause Analysis (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.

5.4 Management Requirements [25]

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

The Laboratory shall conduct management reviews to meet the requirements of ISO/IEC 17025.

5.4.3 Document Control

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

[25] While Articles 5.3.9, 5.3.10 and 5.4.1 – 5.4.5 are described for application by Laboratories in accordance with ISO/IEC 17025 (for testing laboratories), they are also relevant, where applicable, for *ABP* Laboratories within the framework of ISO 15189 (for medical laboratories).

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, ISL *TD*s and ISL *TL*s 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's accreditation status.

c) The Laboratory should also consider implementing the guidance of best practice provided in LGs and TNs in its Management System and SOPs.

5.4.4 Control of Data and Information Management

a) The Laboratory shall keep a copy of all *Sample* records to the extent needed to produce LDOCs or CoAs, in accordance with the ISL *TD* LDOC, in 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*.

5.4.5 Cooperation with Customers and with *WADA*

The Laboratory shall cooperate with customers in accordance with ISO/IEC 17025.

a) Ensuring Responsiveness to *WADA*

   The Laboratory Director or their 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. Report to *WADA* any disruption in the application of mandatory ATP(s) (see ISL *TD* ATP) that may significantly affect the timely reporting of test results. This includes providing the reason(s) for the temporary

unavailability of the Test Method, actions necessary to resolve the situation, and if applicable, which Laboratory(-ies) have been subcontracted to perform the analysis.

v. Provide documentation to *WADA* (e.g., Management System documentation, SOPs, contracts - not including commercial or financial information - with *ADOs*, or with *DTP*s acting on behalf of *ADOs*) 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 ATP(s).

c) Laboratory Expert Opinions

i. The Laboratory shall provide evidence and/or expert testimony on test results or reports produced by the Laboratory as required in administrative, arbitration, or legal proceedings.

ii. The requests for expert testimony from the TA, RMA (if different), *WADA* or hearing bodies as part of the *Results Management* process shall be made in writing.

iii. Laboratory expert opinions shall be in accordance with the ISL Code of Ethics (see Article 8.5).

iv. The Laboratory shall not provide expert testimony directly to *Athletes* or *Athletes*' representatives, including their legal counsels.

v. The Laboratory shall refuse to provide the requested expertise, if it falls outside its competence, knowledge or experience.

[Comment to Article 5.4.5 c): 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.]

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 customers 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 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 ISL *TD*s and ISL *TL*s, as well as by monitoring their performance in the EQAS and during routine Analytical *Testing*.

6.1 *WADA* Laboratory Monitoring

WADA shall monitor the compliance and performance of Laboratories through a series of monitoring and assessment activities, which include but are not limited to:

a) The *WADA* EQAS Program.

b) *WADA* Laboratory Assessments, and

c) Removal of *Samples* for analysis, Further Analysis or *Quality Assurance* purposes.

6.1.1 *WADA* External Quality Assessment Scheme

Laboratories are required to participate in Proficiency Testing or other inter-Laboratory studies to monitor their performance by comparing their results with the results of other Laboratories. In this regard, the EQAS is a valuable Proficiency Testing program for Laboratories to achieve this external quality control surveillance.

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 ISL *TD* EQAS.

6.1.2 *WADA* Laboratory Assessments

WADA reserves the right to inspect and assess Laboratories and *ABP* Laboratories by conducting Document Audits and/or On-site and/or Remote (online) Assessments at any time. In addition, *WADA* performs Assessments of Candidate laboratories and Probationary laboratories as part of PPT and FAT, respectively (see Articles 4.1.2.7 and 4.1.3.8), as well as of Candidate ABP laboratories prior to their *ABP* approval (see Article 4.2.2.6).

As part of an announced or unannounced 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 *WADA* Laboratory Assessments

WADA Laboratory Assessments fall into one of the following two (2) categories:

a) Assessments Related to Laboratory Accreditation or Approval Procedures

This type of Assessment is conducted in relation (but not limited) to the following Laboratory accreditation or *ABP* Laboratory approval procedures:

i. PPT of Candidate laboratories (see Article 4.1.2.7).

ii. FAT of Probationary laboratories (see Article 4.1.3.8).

iii. Approval of *ABP* Laboratory (see Article 4.2.2.6).

iv. Laboratory preparation for Analytical *Testing* during Major *Events* (see Articles 4.3.1.1 and 4.3.2.1).

v. ATR or Suspension of a Laboratory (see Article 7.1.1).

vi. Suspension of an *ABP* Laboratory (see Article 7.6).

b) Assessments Related to *WADA*'s Regular Laboratory Monitoring Activities

As part of *WADA*'s mandate to monitor Laboratory performance, *WADA* has implemented a program of regular Laboratory Assessments. 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 ISL *TD*s and ISL *TL*s.

Scheduling of *WADA* 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 ATPs, or issues with Laboratory operational environment (e.g., lack of independence, customers, 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 within a reasonable timeframe. However, a 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 on an annual basis.

6.1.2.2 *WADA* Laboratory 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 shall 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, *WADA* may invite representative(s) of the AB responsible for the Laboratory's ISO/IEC 17025 (or ISO 15189, as applicable to *ABP* Laboratories) accreditation, as observers during part(s) or the entire duration of the Assessment.

For announced Assessments, *WADA* shall inform the Laboratory, in advance, of the *WADA* Assessment Team composition, as well as the invited AB observers (if applicable). Thereby, the Laboratory shall be provided with the opportunity to lodge an objection, if any, to the appointment of any (non-*WADA* staff) Assessment Team member(s) or AB 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. Furthermore, the Laboratory has the right to lodge justified complaints to *WADA* about the inappropriate behavior of any Assessment Team member (including *WADA* staff) during the Assessment (e.g., unethical behavior, perceived conflicts of interest).

b) Assessment Agenda

For an announced Assessment, *WADA* shall also provide the Laboratory, in advance, a draft Assessment Agenda, as well as requests to provide 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, Test 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 within thirty (30) days, including any identified nonconformities for the Laboratory to implement the necessary improvements. Identified nonconformities shall be addressed by the 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 ISL *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) and pursuant to *Code* Article 6.8, *WADA*, initially at its expense, may remove *Sample*(s) from a Laboratory to conduct analysis or Further Analysis of the *Sample*(s) for the purposes described in *Code* Article 6.2. In such cases, *WADA* shall provide notice [prior to or within a reasonable time after taking possession of the *Sample*(s)] to the Laboratory and to the *ADO*(s) whose *Samples* have been taken (see also *Code* Article 6.8).

[Comment to Article 6.1.3 a): 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 LCOC documentation for all transferred *Samples* and the safety and integrity of the *Samples* until receipt by the receiving Laboratory(-ies).

b) Removal of *Samples* for Laboratory Quality Assessment

WADA may also direct the reanalysis of de-identified *Samples*, which have met the conditions described in Article 5.3.8.2, for purposes of Laboratory Quality Assessment 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 reanalysis may vary.

[Comment to Article 6.1.3 b): A transfer of Samples between Laboratories shall apply only to Samples collected by ADOs or DTPs acting on behalf of ADOs.]

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* as a member(s) of the *Independent Observer Program*. The Laboratory Director and staff shall provide full cooperation and access to the *WADA* observer(s).

WADA, in conjunction with the *MEO* (or *DTP* delegated to undertake *Doping Control* responsibilities for the Major *Event*), 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 also Article 4.3.1.2).

6.2 Evaluation of Laboratory Nonconformities

The *WADA* system of 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 ISL *TDs* and ISL *TLs*. Where applicable, Laboratories should also consider implementing remedial actions to address deviations from recommendations of best practice incorporated in LGs or TNs.

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* Point Scale System, refer to the ISL *TD* PERF.

7.0 Laboratory Disciplinary Procedures

WADA shall regularly review the compliance of Laboratories with the mandatory requirements listed in the ISL and related ISL *TDs* and ISL *TLs*. 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 or *ABP* approval status.

Compliance with all the requirements established in Articles 4.1.4.2 and 4.2.3.2, 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 or *ABP* approval, respectively.

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 ISL *TD*s and/or ISL *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) – see also ISL *TD* PERF.

7.1.1 Analytical *Testing* Restriction or Suspension of *WADA* Accreditation

7.1.1.1 Laboratory Noncompliances that May Lead to an Analytical *Testing* Restriction or Suspension of *WADA* Accreditation

The Lab EAG shall recommend an ATR or the Suspension of a Laboratory's *WADA* accreditation based on, but not limited to, the following noncompliance(s):

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 points for the EQAS and/or Analytical *Testing*, as determined by the application of the Points Scale Table described in the ISL *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 for imposition of an ATR or Suspension of a Laboratory's WADA accreditation are made in consideration of the number of false analytical findings reported by the Laboratory, irrespective of the total number of points accumulated during this period (i.e., after consideration of any applicable 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 an ISL *TD* or ISL *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 ISL *TD*s and/or ISL *TL*s.

i) Serious and repeated noncompliances with results reporting timelines (e.g., frequent significant delays in meeting the recommended reporting deadline without informing the responsible TA(s) or based on invalid reasons such as noncompliances with the implementation of mandatory requirements of the ISL, ISL *TD*s or ISL *TL*s) - see also Article 5.3.6.4 c).

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 Actions, within a reasonable timeframe (as determined by *WADA*), for ISL and/or ISL *TD* and/or ISL *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 5.2.2.4).

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 ISL *TD*s and/or ISL *TL*s identified during *WADA* Laboratory Assessments which demonstrate 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 Analytical *Testing* Restriction

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 ISL *TD*s and/or ISL *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 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 whole blood Samples for the Markers of the Hematological Module of 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 shall inform the Laboratory accordingly.]

7.1.1.3 Cessation of Analytical *Testing*

If a Laboratory has reported a False *AAF* with *Consequences* for an *Athlete*, the Laboratory shall immediately cease all affected analytical activities and inform its customers. The Laboratory shall implement satisfactory Corrective Action(s) to resolve the nonconformity within a reasonable period after notification of the False *AAF* (see ISL *TD* PERF).

a) If the nonconformity is satisfactorily resolved within the established timeframe, *WADA* nevertheless reserves the right to send extra EQAS samples (at the Laboratory's expense) and/or perform an Assessment of the Laboratory (also at the Laboratory's expense) before resuming Analytical *Testing*, at *WADA*'s discretion, and shall use best efforts to notify the Laboratory of such decision in an expedited manner. *WADA*, at its discretion, may also give public notice of the Laboratory's nonconformity, as well as inform stakeholders of the Laboratory's satisfactory resolution of the nonconformity through the implementation of adequate preventive and corrective actions.

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 ATR or Suspension of the Laboratory, as applicable. The Laboratory cessation of Analytical *Testing* shall remain effective 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 the sanction.

In this instance:

a) No right of challenge to the Disciplinary Committee (DC)

   The Laboratory has no right to challenge to the DC the Lab EAG's recommendation 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 Analytical *Testing* Restriction and Suspension of Accreditation – No Disciplinary Proceedings

If a Laboratory has accumulated the maximum allowed number of points for the EQAS and/or Analytical *Testing* (as per the Points Scale Table described in the ISL *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.

a) No right of challenge to the Disciplinary Committee

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 Analytical *Testing* Restriction 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 points detailed in the Points Scale Table in the ISL *TD* PERF, but where the Laboratory's other Analytical *Testing* failure(s) and/or other identified nonconformity(-ies) (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 [26]:

i. Offer the Lab oratory 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.

ii. If the Laboratory does not request a session, the Laboratory shall have the opportunity to either accept the Lab EAG's recommendation 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 recurrence 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 for the Suspension or ATR, Disciplinary Proceedings shall be initiated and conducted in accordance with Article 7.1.3. In such cases, the Lab EAG may issue a recommendation to the Chair of the *WADA* Executive Committee that the Laboratory:

- Continue its Analytical *Testing* activities pending the outcome of the Disciplinary Proceedings, or
- To immediately cease affected Analytical *Testing* activities pending the outcome of the Disciplinary Proceedings. In such cases, a decision by the Chair of the *WADA*

[26] These provisions do not apply in cases of Suspension or ATR pursuant due to a reported False *AAF* with *Consequences* for an *Athlete* (see Article 7.1.1.3) or when the Laboratory has accumulated the maximum allowed number of points for the EQAS and/or Analytical *Testing* (see Article 7.1.1.4).

Executive Committee to impose a Provisional Laboratory Suspension or a Provisional ATR, as applicable, shall not be subject to appeal by the Laboratory.

However, should the Laboratory be immediately subject to a Provisional Laboratory Suspension or a Provisional ATR, the Disciplinary Proceedings before the DC should be conducted within forty-five (45) days of the date when the Provisional Laboratory Suspension or Provisional ATR was imposed.

c) Right of appeal to *CAS*:

If the outcome of the Disciplinary Proceedings leads to an ATR or a Suspension, the Laboratory may appeal the decision of the Chair of the *WADA* Executive Committee 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 Chair of the *WADA* Executive Committee is based on the Laboratory's acceptance of the recommendation for an ATR or a Suspension.

d) 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 (AB).

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 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 points for the EQAS and/or Analytical *Testing* as determined by the application of the Points Scale Table described in the ISL *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).

[Comment to Articles 7.1.2.1 f) and g): Lab EAG recommendations for Revocation of a Laboratory's WADA accreditation are made in consideration of the number of false AAFs and/or False Negative Findings reported by the Laboratory, irrespective of the total number of points accumulated during this period (i.e., after consideration of any applicable point deductions), as well as to whether the Laboratory has satisfactorily corrected the noncompliances.]

h) Failure to correct a noncompliance with any of the requirements or standards listed in the ISL and/or ISL *TD*s and/or ISL *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 ISL *TD*s and/or ISL *TL*s, or repeated failure to implement satisfactory Corrective Action(s) within a reasonable timeframe, as determined by *WADA*, following ISL and/or ISL *TD* and/or ISL *TL* noncompliance(s) identified from *WADA* Laboratory Assessment(s).

j) Serious Laboratory noncompliance(s) with the ISL and/or ISL *TD*s and/or ISL *TL*s identified, for example, during *WADA* Laboratory Assessments, by documented customer 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 analyze the minimum number of *Samples* indicated in Article 4.1.4.2.8.

m) 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).

n) Failure to cooperate with *WADA* or any relevant TA or RMA during a Suspension or ATR period.

o) Analysis of *Samples* from *Signatories* in violation of a Suspension or ATR decision.

p) Repeated and/or continuous failure to cooperate in any *WADA* inquiry in relation to the activities of the Laboratory.

q) Repeated failure to implement and document adequate R&D and Sharing of Knowledge activities.

r) Continuous failure to establish/maintain administrative and operational independence (see Article 4.1.4.2.5), as determined by *WADA*.

s) Loss of support which significantly affects the quality and/or viability of the Laboratory, and/or

t) 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 Analytical *Testing* Restriction 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 noncompliance(s) on which the Revocation recommendation would be based.

During this session, the Laboratory may provide further clarification(s) or evidence of successfully implemented Corrective Actions addressing the nonconformities to prevent their recurrence in the future.

If the Laboratory does not request a session, the Lab EAG shall offer the Laboratory the opportunity to accept the Lab EAG's recommendation 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.

WADA nevertheless reserves the right to send extra EQAS samples (at the Laboratory's expense) and/or perform an Assessment of the Laboratory (also at the Laboratory's expense) before resuming Analytical *Testing*, at *WADA*'s discretion, and shall use best efforts to notify the Laboratory of such a decision in an expedited manner.

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 Laboratory 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 Laboratory Suspension against the Laboratory shall not be subject to appeal by the Laboratory. However, should the Laboratory be immediately subject to a Provisional Laboratory Suspension, the Disciplinary Proceedings before the DC should be conducted within forty-five (45) days of the date when the Provisional Laboratory Suspension of the Laboratory's *WADA* accreditation was imposed.

d) Right of challenge to the Disciplinary Committee

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 shall 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 Analytical *Testing* Restriction or Suspension

a) If the Laboratory is already subject to an ATR or Suspension at the commencement of Revocation procedures, *WADA* shall 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.

WADA shall notify the Executive Committee of the Lab EAG's recommendation for Revocation.

b) Right of challenge to the Disciplinary Committee

If the Laboratory does not accept the Lab EAG's recommendation for Revocation, Disciplinary Proceedings shall be conducted in accordance with Article 7.1.3.

c) 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 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

If a Laboratory challenges the Lab EAG's recommendation for an ATR or Suspension (as per Article 7.1.1.5), or recommendation for Revocation (as per 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 ISL Annex A) to conduct disciplinary proceedings ("Disciplinary Proceedings"). 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 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 (ISL Annex).

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 (ISL Annex).

[Comment to Article 7.1.3: For the avoidance of doubt, and as indicated in Articles 7.1.1.3 and 7.1.1.4, Disciplinary Proceedings shall 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 points for the EQAS and/or Analytical Testing (as determined by the application of the Points Scale Table described in the ISL TD PERF). 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 (ISL Annex), *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 Laboratory 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 Laboratory 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 Analytical *Testing* Restriction

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 Analytical *Testing* Restriction

If *WADA* determines that the noncompliance(s) are limited to a class of *Prohibited Substances* or *Prohibited Methods* or to a specific ATP, 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 Substances* or *Prohibited Methods* or for the specific ATP in which the noncompliance(s) occurred.

Following the ATR notification by *WADA*, the Laboratory shall:

a) Inform its customers of the imposed ATR.

b) Immediately cease all analyses employing the affected ATP(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 [27] 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 of the same class of *Prohibited Substances* or *Prohibited Methods* and/or the application of the ATP(s) subjected to the ATR) to a subcontracted Laboratory(-ies) for the performance of the "A" and, if needed, the "B" CP(s) (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 PAAF(s).

   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 *Sample*(s), reported as Negative Finding(s) and still stored in the Laboratory, may have been impacted, the Laboratory shall inform the TA and *WADA*.

[27] 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 costs associated with the transfer of *Samples* shall be borne by the Laboratory under ATR.

In such cases, both the "A" and "B" containers of the relevant *Samples* shall be transferred 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 ATP(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 on the analysis of the *Markers* of the Hematological Module of 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(s) and CP(s), if needed) and "B" analysis (if requested), unless otherwise instructed by *WADA* [28]:

   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.

[28] The suspended 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 decision. All costs associated with the transfer of *Samples* shall be borne by the Laboratory under Suspension.

Any additional costs of analysis to those previously agreed or already paid to the suspended Laboratory shall be borne by the Laboratory under Suspension. In the case of ISL Code of Ethics violation(s), the suspended Laboratory shall also reimburse the TA for the costs of reanalysis in another Laboratory. The suspended 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).

e) Suspension for Violation of the ISL Code of Ethics

The Laboratory shall transfer all *Samples* (both the "A" and "B" *Samples*) in the Laboratory's custody to another Laboratory(-ies) chosen by the relevant TA(-ies).

f) Suspension for Reporting of False *AAF*

The Laboratory shall transfer *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 to another Laboratory(-ies) to reconduct the ITPs and, if needed, to perform the CP(s). 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 ATP(s) that were associated with the Negative Finding, as determined by *WADA.*

ii. If the Laboratory's investigation reveals that other *Sample*(s) already reported as Negative Finding(s) may have been impacted (including *Sample*(s) that have been placed in long-term storage upon request by the TA, RMA or *WADA*), the Laboratory shall inform the TA, RMA (if different) and *WADA*. In such cases, both the "A" and "B" containers of the relevant *Sample*(s) shall be transferred 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* and/or *Prohibited Methods* or to the ATP(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 to another Laboratory(-ies) for the "A" CP(s) to be repeated and to perform the "B" CP(s), if applicable.

i) Suspension Related to the Analysis of the *Markers* of the Hematological Module of the *ABP*

If the Suspension concerns the analysis of the *Markers* of the Hematological Module of the *ABP*, whole blood *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 stability of the blood cells targeted for the analysis of the Markers of the Hematological Module of the ABP, it is not normally feasible to send the whole blood Samples to other Laboratory(-ies) for this 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 of the relevant *Samples* to a Laboratory(-ies).

c) A revoked laboratory shall arrange the transfer 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 [29].

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

[29] The revoked laboratory shall contact the relevant TA(-ies) to arrange for the transfer of *Samples* to a Laboratory(-ies), chosen by the TA, within thirty (30) days of being notified of the Revocation decision. All costs associated with the transfer of *Samples* shall be borne by the laboratory subject to Revocation.

Any additional costs of analysis to those previously agreed or already paid to the revoked laboratory shall be borne by the laboratory subject to Revocation. In the case of ISL Code of Ethics violation(s), the revoked laboratory shall also reimburse the TA for the costs of reanalysis in a Laboratory. The 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).

Laboratory(-ies) that have been selected to receive the *Samples* (see also 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).

e) All costs associated with the transfer of *Samples* shall be covered by the revoked laboratory.

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 ISL *TD* and/or ISL *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 AB 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* shall 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 Laboratory 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 twelve (12)-month extended Suspension or ATR, 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 customers of the decision to cease its operations and to arrange, in consultation with its customers, the transfer of *Samples* to another Laboratory(-ies).

7.4.1 Temporary Closure of Laboratory Operations

If a Laboratory voluntarily ceases its anti-doping Analytical *Testing* operations on a temporary basis, the Laboratory shall:

a) Transfer *Samples* to another Laboratory(-ies) in accordance with Article 7.2.2.

b) Maintain its participation in the *WADA* EQAS with satisfactory performance during the period of inactivity.

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).

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*.

7.4.2 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 Analytical *Testing* Restriction

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. This may include the Laboratory analysis of additional EQAS samples and/or the conduct of a *WADA* Laboratory Assessment, at any time and at the expense of the Laboratory, to evaluate the Laboratory's status. If all conditions are met, the lifting of the Suspension or the ATR may occur before the end of the minimum applicable sanction period, as determined by WADA.

7.5.2 Re-accreditation after Revocation

If a laboratory whose *WADA* accreditation has been revoked wishes to seek a new *WADA* accreditation, it shall apply as a new Applicant 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 shall be followed prior to granting an expedited re-accreditation process.

7.6 Suspension or Revocation of *ABP* Laboratory

An *ABP* Laboratory's *WADA* approval may be suspended or revoked whenever the *ABP* Laboratory fails to comply with the ISL and/or applicable ISL *TD*s and/or ISL *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 whole blood *Samples* and the Analytical *Testing* process for the Hematological Module of 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 and 7.1.2, 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 (ISL Annex).

c) Due to the negative impact of time on the stability of the blood cells targeted for the analysis of the *Markers* of the Hematological Module of the *ABP*, it is not normally feasible to send the whole blood *Samples* to other Laboratory(-ies) or *ABP* Laboratory(-ies) for this analysis after Suspension or Revocation of a laboratory's *WADA* approval for the *ABP*.

d) *WADA* shall lift the Suspension only when the *ABP* Laboratory provides satisfactory evidence, as determined by *WADA*, that appropriate steps have been taken to remedy the noncompliance(s) that resulted in the Suspension, 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 ABP* approval, it shall apply as a new Applicant *ABP* 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 ATP(s) (immediate provisional ATR).

ii. Inform the responsible RMA (i.e., the *MEO* or *DTP* delegated to undertake *Results Management* responsibilities for the Major *Event*) and *WADA.*

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* based on the application of the ATP(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 (see also ISL *TD* PERF).

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 responsible RMA (i.e., the *MEO* or *DTP* delegated to undertake *Results Management* responsibilities for the Major *Event*) and *WADA.*

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 based on the application of the ATP(s) for which the noncompliance occurred (see also ISL *TD* PERF).

iv. The Corrective Actions implemented, and the results of the reanalysis 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, shall result in the imposition of a Suspension or an ATR, as determined by *WADA*, and the cessation of Analytical *Testing* during the Major *Event* (see also ISL *TD* PERF). The procedure for the imposition of a Suspension or an ATR shall follow the provisions of Article 7.1.1 *mutatis mutandis*.

8.0 Code of Ethics for Laboratories

8.1 Confidentiality

Laboratory Directors, their delegates and all Laboratory staff shall respect and comply with Article 5.3.6.3 and *Code* Article 14.3.5.

8.2 Research in Support of *Doping Control*

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

The Laboratories are expected to develop a 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 Laboratory shall follow the Helsinki Declaration and any applicable national standards as they relate to the involvement of human subjects in research (see also *Code* Article 19.4). Voluntary informed consent shall also be obtained from human subjects in any drug administration studies for the purpose of developing a RC or proficiency testing materials.

Athletes who may undergo *Doping Control Testing* by *ADOs* shall not be the subjects of drug administration studies that include *Prohibited Substances* or *Prohibited Methods* (see also *Code* Article 19.5).

8.2.2 Controlled Substances

The Laboratory is 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 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 ADOs.]

8.3.1 Analytical *Testing* for *ADO*s

The Laboratory shall accept *Samples* for Analytical *Testing* from *ADO*s only (see also Article 5.3.2) if all the following conditions have been met:

a) The *Sample* matrix is of the proper type (e.g., urine, whole blood, DBS) for the requested analyses.

b) The *Samples* have been collected, sealed, and transported to the Laboratory in accordance with the *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.

8.3.2 Analytical *Testing* for Non-*Signatories*

a) The Laboratory shall not accept *Samples* directly from individual *Athletes* or from individuals or organizations acting on their behalf.

b) The Laboratory may accept samples from non-*Signatories* for analysis; however, 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 analytical activity is covered under the Laboratory's WADA-accredited or -ABP 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 shall not provide analytical services as part of a *Results Management* or *Doping Control* adjudication process, unless specifically requested by the responsible 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 RMA or a hearing body as part of a *Results Management* or adjudication process. If a request is made by an *Athlete*, the Laboratory may conduct the analysis if agreed by the RMA, which may also specify conditions that shall be followed prior to or during the analysis (e.g., verification of original sealed packages, product batch number); or

b) If done as part of a legitimate anti-doping research program, as determined by *WADA*.

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 8.3.3 and 8.3.4 shall 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 -ABP 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* shall 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 specific details of Analytical Methods, working with WADA to produce and/or distribute new RMs or RCs 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 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 ISL *TD* EQAS).

b) All employees of 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 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 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 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 is requested to provide evidence in anti-doping proceedings, they are expected to provide independent, scientifically valid expert testimony.

g) The Laboratory shall not issue any statements related to its analytical processes or findings, unless otherwise provided in *Code* Article 14.3.5. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be the sole responsibility of the responsible *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 being subject to Disciplinary Proceedings instituted by *WADA* to suspend or revoke its *WADA* accreditation or its *WADA* approval, as applicable, in accordance with 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 being subject to disciplinary action by the Laboratory, 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 ANNEXES AND APPENDICES

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 Articles 7.1.2.2 or 7.1.2.3 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 shall 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* shall 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 timeframe, the Disciplinary Proceedings shall continue based on the evidence at the disposal of the DC.

Article A-4

Unless both parties agree or the Chairperson, at their 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 Article A-3 above. Any determination made by the Chairperson pursuant to this Article A-4 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 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 ISL *TDs* or ISL *TLs*, 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 [30], 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 communication to the parties that no hearing shall 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 ISL *TDs* and/or ISL *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 ISL *TD* and/or ISL *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 *WADA* Laboratory Assessment conducted 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 is considered 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.

[30] 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 shall 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 accreditation shall be made shortly prior to the commencement of a Major Event or Event or 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 ISL *TD*s and/or ISL *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.

APPENDIX 1: DEFINITIONS

I. Defined Terms from the 2027 *Code* that are used in the ISL

***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 *National Anti-Doping Organization*s.

***Athlete*:** Any *Person* who competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each *National Anti-Doping* Organization). An *Anti-Doping Organization* has discretion to apply anti-doping rules to an *Athlete* who is neither an *International-Level Athlete* nor a *National-Level Athlete*, and thus to bring them within the definition of "*Athlete*." In relation to *Athletes* who are neither *International-Level* nor *National-Level Athletes*, an *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 *Therapeutic Use Exemptions*. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any *Athlete* over whom an *Anti-Doping Organization* has elected to exercise its authority to test and who competes below the international or national level, then the *Consequences* set forth in the *Code* shall 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*.

[Comments to Athlete: For the avoidance of doubt, an Anti-Doping Organization may not adopt different rules for such Athletes (including with respect to Therapeutic Use Exemptions) except with respect to the matters explicitly referenced above or as expressly allowed by an International Standard.

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

***Athlete Biological Passport* (*ABP*):** The program and methods of gathering and collating data as described in the *International Standard* for *Testing* and *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*), 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 10.14; (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 ISL TD DL and other applicable Technical Documents (e.g., ISL TD GH, ISL TD CG/LH).]

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

***Doping Control*:** All steps and processes from test distribution planning through to ultimate disposition of any appeal and the enforcement of *Consequences*, including all steps and processes in between, including but not limited to, *Testing*, investigations, whereabouts, *Therapeutic Use Exemptions*, *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 p.m. 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.]

Independent Observer Program: A team of observers and/or auditors, under the supervision of *WADA*, who observe and provide guidance on the *Doping Control* process prior to or during certain *Events* and report on their observations as part of *WADA*'s compliance monitoring program.

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

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

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

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

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

***Minimum Reporting Level* (*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 MRLs and the Non-Threshold Substances to which they shall be applied, refer to the ISL TD MRL or to the relevant Technical Letter(s).]

Monitoring Program: Laboratory Analytical Testing program including substances or methods that are not in the *Prohibited List*, but that *WADA* wishes to monitor in order to detect potential patterns of misuse in sport.

***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*, manage test results, and conduct *Results Management* at the national level. If this designation has not been made by the competent public authority(ies), the entity shall be the country's *National Olympic Committee* or its designee.

***National Olympic Committee* (*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 *National Olympic Committee* 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., *Atypical Finding*, *Athlete Biological Passport*, whereabouts failure), such pre-notification steps expressly provided for in Article 5 of the *International Standard* for *Results Management*, through the charge until the final resolution of the matter, including the end of the hearing process at first instance or on appeal (if an appeal was lodged).

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

[Comment to Sample or Specimen: It has sometimes been claimed that the collection of blood or urine 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 accepting the *Code* and agreeing to implement the *Code*, as provided in Article 23.

***Tampering*:** Intentional conduct which subverts the *Doping Control* process. *Tampering* shall include, without limitation, offering or accepting a bribe to perform or fail to perform an act, preventing the collection of a *Sample*, affecting or making impossible the analysis of a *Sample*, falsifying documents submitted to an *Anti-Doping Organization* or *Therapeutic Use Exemption* committee or hearing panel, procuring false testimony from witnesses, committing any other fraudulent act upon the *Anti-Doping Organization* or hearing body to affect *Results Management* or the imposition of *Consequences*, and any other similar intentional interference or *Attempted* interference with any aspect of *Doping Control*.

[Comment to Tampering: For example, this Article would prohibit altering identification numbers on a Doping Control Form during Testing, breaking the B bottle at the time of B Sample analysis, altering a Sample by the addition of a foreign substance, or intimidating or Attempting to intimidate a potential witness or a witness who has provided testimony or information in the Doping Control process. Tampering includes misconduct which occurs during the Results Management process. See Code Article 10.9.3.3. However, actions taken as part of a Person's legitimate defense to an anti-doping rule violation charge shall not be considered Tampering. Sample collection personnel should be permitted to carry out their duties in a safe environment without interference or harassment. Offensive conduct towards a Doping Control official or other Person involved in Doping Control which does not otherwise constitute Tampering shall be addressed in the disciplinary rules of sport organizations.]

***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 relating to the analysis, interpretation and reporting of specific *Prohibited Substance(s)* and/or *Prohibited Method(s)* or to the application of specific Laboratory or *Athlete Biological Passport* Laboratory procedures.

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

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

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

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

II. Defined Terms Specific to the ISL

***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 *Athlete Biological Passport* (*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 are referred to as "Laboratory(-ies)". If, instead, provisions apply exclusively to either Laboratories or ABP Laboratories, the specific definition is used as applicable.

Instead, when the term "laboratory" is used, it implies laboratories that are neither WADA-accredited nor ABP approved.]

Aliquot: A portion of the *Sample* of biological fluid (e.g., urine, blood) obtained from the *Athlete* that is 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 (ATP) 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* Procedure (ATP) or Test Method.

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

Analytical *Testing* Procedure (ATP): A Fit-for-Purpose procedure, as demonstrated through method validation, which is used to detect, identify and/or quantify property values of Analyte(s) in a *Sample* for *Doping Control* purposes in accordance with the ISL and relevant ISL *Technical*

Documents, Technical Letters or Laboratory Guidelines. An Analytical *Testing* Procedure is also referred to or known as an Analytical Method or Test Method.

Analytical *Testing* Restriction (ATR): Restriction on a Laboratory's application of specified Analytical *Testing* Procedure(s) (ATP) 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, associated with a Laboratory, composed of a *Person* or *Persons* responsible for the timely management of *Athlete Biological Passports* in *ADAMS* on behalf of the Passport Custodian.

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

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

Certificate of Analysis (CoA): The material produced by a Laboratory upon request by an APMU, Expert Panel, or *WADA* as set forth in the ISL *Technical Document* on Laboratory Documentation Packages (ISL *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): Reference Material, 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 Measurement Uncertainty, and a statement of metrological traceability.

Confirmation Procedure (CP): An Analytical *Testing* Procedure (ATP) that has the purpose of confirming the presence (Qualitative Procedure) and/or determining the property value (Quantitative Procedure) of one or more Analytes in a *Sample*.

External Quality Assessment Scheme (EQAS): Program for Quality Assessment of Laboratory performance. The EQAS includes the periodical distribution of urine, blood or DBS *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 Laboratories and *ABP* Laboratories for the analysis of the *ABP* blood *Markers* (hematological, endocrine and steroidal *ABP Markers*).

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 ISL *Technical Documents* and *Technical Letters*.

Flexible Scope of ISO/IEC 17025 Accreditation: Status of laboratory accreditation, which allows a Laboratory to make and implement restricted modifications in the Scope of ISO/IEC 17025 Accreditation between Assessments by the Accreditation Body.

[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 the Markers of the Hematological Module of the ABP when included in the Scope of ISO 15189 Accreditation of ABP Laboratories.]

Further Analysis: Further Analysis occurs when a Laboratory conducts additional analysis on an "A" *Sample* or a "B" *Sample* after the final analytical result for that "A" *Sample* or that "B" *Sample* has been reported by the Laboratory. Any Further Analysis initiated by an *Anti-Doping Organization* (*ADO*) shall be conducted at the expense of the *ADO.*

Independent Witness: A *Person*, invited by the *Testing* Authority (TA), the Laboratory or *WADA* to witness the opening and initial aliquoting of an *Athlete's* "B" *Sample*, or the splitting of an "A" or "B" *Sample*. An Independent Witness shall not be an employee or have a personal financial relationship with the *Athlete* or their representative(s), the Laboratory, the *Sample* Collection Authority (SCA), the TA / *Delegated Third Party* (*DTP*) / *Results Management* Authority (RMA) or *WADA*, as applicable. However, this does not apply to *Persons* from other areas of the Laboratory's umbrella organization (e.g., other laboratories within the university or research institution). The Independent Witness may be indemnified for their service.

Initial *Testing* Procedure (ITP): An Analytical *Testing* Procedure (ATP) whose purpose is to screen for the possible presence of an Analyte(s) or for elevated property value(s) of an Analyte(s) in a *Sample.*

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 are referred to as "Laboratory(-ies)". If, instead, provisions apply exclusively to either Laboratories or ABP Laboratories, the specific definition is used as applicable.

Instead, when the term "laboratory" is used, it implies laboratories that are neither WADA-accredited nor ABP approved.]

Laboratory Chain of Custody (LCOC): Information registered by the Laboratory, in accordance with ISL *TD* LCOC requirements, to record, in writing or electronically, the chronological traceability of custody (by authorized *Person(s)* or upon storage) and movement of the *Sample* and any Aliquot of the *Sample* taken for Analytical *Testing*.

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

[Comment to Laboratory Documentation Package: Laboratories and ABP Laboratories may also produce ABP LDOCs, if requested by the 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, recommendations and guidance to *WADA* with respect to the overall management of anti-doping Laboratory accreditation and *ABP* approval processes, the production and maintenance of the ISL and associated normative documents (ISL *Technical Documents, Technical Letters*, Laboratory Guidelines and Technical Notes), and the monitoring of Laboratory performance.

[Comment to Laboratory Expert Advisory Group: The Lab EAG's membership composition and Terms of Reference can be found on WADA's website.]

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.

Limit of Detection (LOD): Parameter of Qualitative Procedure 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): Parameter of technical performance of chromatographic-mass spectrometric confirmatory Qualitative Procedures. For a given Analyte (for which a Reference Material is available), the LOI of a Test Method shall be determined at 95% identification rate and shall be less than the corresponding Minimum Required Performance Level (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 an Adverse Analytical Finding (AAF) or an Atypical Finding (ATF), as applicable, when the Analyte is identified in the Sample according to the criteria established in the ISL Technical Document on Chromatographic-Mass Spectrometric Identification Criteria (ISL TD IDCR).]

Limit of Quantification (LOQ): Parameter of Quantitative Procedure technical performance. Lowest concentration of an Analyte in a *Sample* that can be quantitatively determined with acceptable intermediate precision and bias (i.e., acceptable Measurement Uncertainty) under the stated Test Method conditions.

Major *Event*: A continental, regional or other *International Event*, conducted under a *Major Event Organization* functioning as a ruling body (e.g., the Olympic and Paralympic Games, Pan American Games), for which the *Testing* program significantly exceeds the routine operational capabilities of the Laboratory (e.g., number of *Samples*, results reporting times, Analytical *Testing* menu).

Measurement Uncertainty (MU): Doubt about the property value (e.g., concentration, ratio, score, or any other measurable analytical variable, as defined by *WADA*) that remains after making a measurement using a Quantitative Procedure.

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 the presence of an Analyte in *Samples* during the routine daily operation of the Laboratory. Individual Laboratories may and are expected to achieve better performance [see ISL *Technical Documents*: ISL *TD* MRPL, ISL *TD* EPO, ISL *TD* DBS).

Negative Finding: A test result from a Laboratory which, in accordance with the effective ISL and/or relevant ISL *Technical Documents* and/or ISL *Technical Letters*, concludes that no Analyte included in the requested Analytical *Testing* menu was found in a *Sample* based on the applied Initial *Testing* Procedures (ITPs) and/or Confirmation Procedures (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 *Adverse Analytical Finding* (*AAF*). Some Non-Threshold Substances have an associated *Minimum Reporting Level* (*MRL*).

Presumptive *Adverse Analytical Finding* (PAAF): The status of a *Sample* test result from the Initial *Testing* Procedure (ITP) which represents a suspicious finding, but for which a Confirmation Procedure (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 Laboratory Suspension: Temporary Suspension of a Laboratory's *WADA* accreditation or *ABP* approval pending a final decision by *WADA* regarding its accreditation or approval status.

Qualitative Procedure: An Analytical *Testing* Procedure (ATP) that has the purpose of screening for (Initial *Testing* Procedure) or confirming the presence of (Confirmation Procedure), according to established identification criteria, one or more Analytes in a *Sample*.

Quantitative Procedure: An Analytical *Testing* Procedure (ATP) that has the purpose of determining the property value (e.g., concentration, ratio, score, or any other measurable analytical variable, as defined by *WADA*) of one or more Analytes in a *Sample*.

Reference Collection (RC): A sample 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 or from *in vitro* studies in which the presence of the substance of interest has been established.

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

Revocation: The permanent withdrawal of a Laboratory's *WADA* accreditation or *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 Method to determine, accurately and specifically, the Analyte of interest in the presence of other components in a *Sample* matrix under the stated conditions of the Analytical Method.

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

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

Test Method: Analytical *Testing* Procedure (ATP), Analytical Method.

Threshold: The maximum permissible level of a property value (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) for an Analyte(s) of a Threshold Substance in a *Sample*. The Threshold is used to establish the *Decision Limit* (*DL*) for reporting an *Adverse Analytical Finding* (*AAF*) for a Threshold Substance.

Threshold Substance: A *Prohibited Substance* for which the identification and quantitative determination of a property value (e.g., concentration, ratio, score, or any other measurable analytical parameter, as defined by *WADA*) of an Analyte in excess of a pre-determined *Decision Limit* (*DL*), or, when applicable, the establishment of an exogenous origin, constitutes an *Adverse Analytical Finding* (*AAF*). Threshold Substances are identified as such in the ISL *Technical Document* on *Decision Limits* (ISL *TD DL*) and other applicable ISL *Technical Documents*.

III. Defined Terms from the *International Standard* for *Results Management* used in the ISL

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*.

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

IV. Defined Terms from the *International Standard* for *Testing* that are used in the ISL

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

***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 *Testing* Authority itself; or (2) a *Delegated Third Party* to whom the authority to conduct *Testing* has been granted or sub-contracted. The *Testing* Authority always remains ultimately responsible under the *Code* for compliance with the requirements of the *International Standard* for *Testing* relating to collection of *Samples*.

***Sample* Collection Session (SCS):** 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 *Anti-Doping Organization* that plans *Testing* on *Athletes*, in accordance with the requirements of Article 4.7 (of the *International Standard* for *Testing*).

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