2027 CODE & IS UPDATE PROCESS

Second Draft: Summary of Major Changes

International Standard for Laboratories

Executive Summary

Following the careful review and consideration of stakeholder comments provided during the Stakeholder Consultation Phase, the International Standard for Laboratories Drafting Team has proposed further key changes in a second draft of the 2027 International Standard for Laboratories (ISL) as part of the ongoing 2027 Code & IS Update Process.

The purpose of this document is to summarize the major changes proposed in the second draft of the 2027 ISL, which predominantly build on those proposed in the first draft of the 2027 ISL and as summarized in the corresponding first draft Summary of Major Changes.

It is to be noted that any new changes in the second draft of the 2027 ISL, which do not otherwise stem from or build on those changes indicated in the first draft, will be accordingly marked as "New Addition". Particularly, in this respect, the ISL Drafting Team wishes to draw the attention of stakeholders to the following new additions which have been included in this second draft:

- Four (4) new Technical Documents (TDs) have been produced, and the drafts will be circulated for stakeholders' comments together with the second draft of the 2027 ISL. These new TDs shall become effective at the same time as the 2027 ISL:
    - Method Validation Requirements (TD VAL);
    - External Quality Assessment Scheme (TD EQAS);
    - WADA Laboratory Performance Evaluation System (TD PERF); and
    - Analytical Testing Procedures (TD ATP).
- New ISL definitions of Qualitative Procedure and Quantitative Procedure have been incorporated.
- Decisions of the WADA Executive Committee to revoke a laboratory's candidate or probationary status shall be provided to the laboratory in writing.
- Considering recent developments in the international laboratory accreditation system, reference to the International Laboratory Accreditation Cooperation (ILAC) has been replaced by the Global Accreditation Cooperation.
- The ISL Drafting Team agreed to the proposal of including the possibility for an accredited laboratory to use validated Initial Testing Procedures that are not included in the laboratory's ISO/IEC 17025 Scope of Accreditation or for which analytical/reporting requirements have not been defined by WADA. Any Samples producing a Presumptive Adverse Analytical Finding (PAAF) shall be retained in the laboratory until the confirmation/reporting requirements have been established by WADA (in a TD, TL or LGs) and the laboratory, in consultation with the Testing Authority (TA), proceeds to confirming the result using a validated Confirmation Procedure.

- For testing for a Major Event, emphasis has been placed on the existence of a written agreement between the Major Event Organization (MEO) and the laboratory with respect to Analytical Testing requirements. Such an agreement shall be reached sufficiently ahead of the Major Event (e.g., at least six (6) months before the Olympic and Paralympic Games). It has also been added that, as part of its laboratory assessments in preparation for a Major Event, WADA will inform the TA/MEO of any identified Major Nonconformity (MNC) which represents a serious risk in the laboratory's ability to conduct the required Analytical Testing menu for the Major Event. Furthermore, it has been clarified that the submission by WADA of double-blind EQAS samples for evaluation of Laboratories while testing during a Major Event shall be at the request and at the expense of the MEO.

Furthermore, the ISL Drafting Team wishes to mention certain other key developments which arose from its review of stakeholder comments and discussions with the anti-doping community during the Second Drafting Phase:

- Acronyms for terms defined in the Code or the International Standards are defined besides the corresponding full name of the term in Article 3.0 Terms and Definitions. Then, the acronyms are used throughout the document. For those terms that are not defined in Code or the International Standards, if acronyms are used, they are defined the first time the term is used in the document.
- A better use of the term "Laboratory", which incorporates both WADA-accredited laboratories and WADA-approved ABP laboratories, has been made throughout the document when referring to requirements that are applicable to both types of laboratories.
- Several ISL definitions have been modified for better clarity (see further below).
- Additional examples of Technical Documents have been listed in Article 3.5.
- It has been clarified that Laboratory Guidelines (LGs) are models of best practice, and therefore their implementation is not mandatory for purposes of laboratory compliance. Accordingly, mention of LGs has been removed throughout the document when referring to mandatory requirements.

The following section offers a concise article-by-article summary of the changes in this second draft of the 2027 ISL, where applicable. Where no changes have occurred between the first and the second drafts of the ISL 2027, the Article number will not be listed below.

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

Section 1.0: Introduction and Scope

Changes from the First Draft

Article 1.1.1: International Standard for Laboratories (ISL)

Following the review of stakeholder comments, the ISL Drafting Team has decided to remove the first paragraph from this Article, which refers to the purpose and implementation of the International Standards in the introduction to the Code. The ISL Drafting Team has considered that it is not necessary to repeat this introduction in the ISL while focusing this Article on describing the purpose and main requirements of the ISL.

Article 1.1.2: Technical Documents

While the main proposed changes to this Article, as indicated in the first draft, remain unamended, there have been further editorial changes to the wording and organization of this Article in the second draft to further facilitate its understanding.

Article 1.1.3 Technical Letters

The main proposed changes to this Article, as indicated in the first draft, remain unamended; however, there have been further editorial changes to the wording and organization of this Article in the second draft to further facilitate its understanding.

Article 1.15 Technical Notes (TNs)

NEW ADDITION

While TNs remain confidential to laboratories, it has been clarified that the laboratory may provide hard copies of TNs to representatives from ISO/IEC 17025 Accreditation Bodies, confidentially and upon request, for use during the course of Laboratory assessments.

Section 3.0: Definitions and Interpretations

Changes from the First Draft

The name of this section has been changed to "**Terms and Definitions**".

Article 3.1: Defined terms from the Code that are used in the ISL

A comment has been added to the definition of Minimum Reporting Level (MRL) to refer to the TD MRPL or to specific Technical Letters for more information on MRLs and the Non-Threshold Substances to which they shall be applied.

Article 3.1: Defined terms in the ISL

NEW ADDITION

The following two new definitions were added to clarify the difference between qualitative and quantitative procedures:

- Qualitative Procedure;
- Quantitative Procedure.

In addition, applicable adjustments have been made to the following ISL definitions:

- Athlete Passport Management Unit (APMU);
- Confirmation Procedure (CP);
- External Quality Assessment Scheme (EQAS);
- Further Analysis: the comment on Further Analysis has been removed and transferred to the main body of the Standard in Article 5.3.4.3 – Further Analysis;
- Initial Testing Procedure (ITP);
- Laboratory Chain of Custody (LCOC);
- Laboratory Expert Advisory Group (Lab EAG);
- Limit of Identification (LOI);
- Limit of Quantification (LOQ);
- Major Event;
- Selectivity; and
- Threshold Substance.

Some other definitions were also the subject of minor editorial changes.

Article 3.5: TDs cited in this version of the ISL

NEW ADDITION

The following two new TDs were added to the list of TDs cited in the ISL:

- TD ATP – Analytical Testing Procedures; and
- TD GD – Gene Doping Detection based on Polymerase Chain Reaction (PCR).

In addition, a footnote (footnote 3) has been added to clarify that additional new TDs may be drafted and published by WADA, which will not be cited in this version of the ISL and, therefore, will not be listed in this ISL Article. Such new TDs shall nevertheless be considered an integral part of the ISL and will supersede any previous publication on a similar topic, including TLs and/or the ISL.

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

Section 4.0: Process and Requirements for WADA Laboratory Accreditation and ABP Laboratory Approval

Changes from the First Draft

Article 4.1.1: Applicant laboratory for WADA Accreditation

It has been clarified that the decision of the WADA Executive Committee to accept or deny a laboratory's application shall be provided to the Applicant laboratory in writing.

Article 4.1.1.2: Submit Initial Application Form

The main proposed changes to this Article, as indicated in the first draft, remain unamended; however, a comment has been added to clarify that, exceptionally, WADA may consider accepting an Applicant laboratory from a country where the National Anti-Doping Program does not meet the minimum Sample number requirements, if that application is supported by other Anti-Doping Organizations (ADOs) in the region which would guarantee a robust Regional Anti-Doping Program. This opens the possibility to Applicant laboratories from small countries which, once accredited, may offer anti-doping testing services to other countries in their region.

Article 4.1.2: Candidate laboratory for WADA Accreditation

It has been clarified that the decision of the WADA Executive Committee on whether an Applicant laboratory will be granted WADA Candidate laboratory status shall be provided to the Applicant laboratory in writing.

Article 4.1.2.5: Mentoring Agreement

NEW ADDITION

This is a new Article, which has been added to reinforce the importance of establishing mentoring agreements (contracts or Memorandums of Understanding) between candidate laboratories and WADA-accredited laboratories to ensure successful preparation of the candidate laboratory towards obtaining *WADA* accreditation. The second part (part (b)) of the Article, refers the need for the candidate laboratory to obtain authorization from

WADA to receive sensitive anti-doping information and/or access to specific, WADA-developed anti-doping tests or materials.

Article 4.1.2.8: Duration of Candidate Phase of WADA Accreditation

It has been clarified that WADA shall review each reapplication (or a revoked candidate laboratory) on its own merits on a case-by-case basis and retains the right to reject repeated applications.

Article 4.1.3: Probationary laboratory for WADA Accreditation

The main proposed changes to this Article, as indicated in the first draft, remain unamended. However, the order of subarticles within 4.1.3 has been modified to better reflect the different steps of the probationary phase of WADA accreditation. In addition, the following 4.1.3 subarticles were subjected to modifications:

Article 4.1.3.7: Analytical Testing Procedures

The ISL Drafting Team included clarifications in this Article regarding the Analytical Testing Procedure requirements for candidate laboratories for entering the probationary phase of accreditation, as well as for probationary laboratories to be ready for the Final Accreditation Test (FAT).

Article 4.1.3.9: Obtaining ISO/IEC 17025 Accreditation by the Probationary laboratory

It has been clarified that a Probationary laboratory shall obtain ISO/IEC 17025 accreditation before the end of the probationary period (i.e., before WADA grants accreditation) and, if possible, before the FAT. In addition, reference is made to the Accreditation Body being a full member of the Global Accreditation Cooperation and a signatory to the Mutual Recognition Arrangement (MRA) of the Global Accreditation Cooperation.

Article 4.1.3.12: Duration of Probationary Phase of *WADA* Accreditation

It has been clarified that the decision of the WADA Executive Committee to revoke a probationary laboratory status shall be provided to the laboratory in writing.

Article 4.1.4: WADA-Accredited Laboratory

Article 4.1.4.2.4: Maintain ISO/IEC 17025 Accreditation

Again, in this Article, the reference to ILAC and the ILAC MRA has been replaced by the Global Accreditation Cooperation and MRA of the Global Accreditation Cooperation.

Furthermore, the ISL Drafting Team considered it important to clarify that Laboratories may apply Analytical Testing Procedures, which are not within the laboratory's Scope of ISO/IEC17025 Accreditation, to the analysis of doping control Samples only under exceptional circumstances, upon informing WADA, and after having validated the method in conformity with ISO/IEC17025 accreditation and ISL requirements, including its applicable TD(s) and TL(s). This has been exemplified in a comment, which describes the application of non-accredited Initial Testing Procedure(s) that, if producing Presumptive Adverse Analytical Findings, would lead to the retention of the Sample(s) until the finding can be confirmed with a validated Confirmation Procedure in conformity with requirements established by WADA. This article also references the new TD ATP to obtain more information on WADA-specific Analytical Testing Procedures.

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

Many of the proposed changes to this Article, as indicated in the first draft, remain unamended. However, the following additional modifications have been incorporated:

- It has been clarified that encrypted email, or other written forms of WADA-approved secure communication, with confirmation of receipt, shall be accepted to report information on new doping substance(s), method(s), or practice(s).
- The requirement for the laboratory to have a Research & Development (R&D) department/unit was removed, since this is not considered compatible with all possible laboratory internal organizations or numbers of staff. Instead, the requirements are focused on maintaining a sustainable R&D strategy and long-term plan, including objectives, planned deliverables, timelines, and a knowledge dissemination scheme.
- The requirements of the qualified person(s) responsible for R&D activities have been transferred to Article 5.2.2 (subarticle 5.2.2.3) that deals with Laboratory Personnel.

Article 4.1.4.2.11: Participating in WADA / Accreditation Body (AB) Assessments

It has been clarified that AB shall be a full member of the Global Accreditation Cooperation and a signatory to the MRA of the Global Accreditation Cooperation.

Article 4.2: WADA ABP Laboratory Approval

Article 4.2.1: Applicant ABP laboratory

It has been clarified that the decision of the WADA Executive Committee to accept or deny a laboratory's application shall be provided to the Applicant ABP laboratory in writing.

Article 4.2.1.2: Submit Initial Application Form

The main change to this Article, in comparison to the first draft, is the increase from 200 to 300 in the number of blood ABP Samples that the National Anti-Doping Organization (NADO) of the Applicant ABP laboratory's host country shall have collected, in compliance with the IST, in the most recent full year. In addition, a comment has been added to clarify that, exceptionally, WADA may consider accepting an Applicant ABP laboratory from a country where the National Anti-Doping Program does not meet the minimum blood ABP Sample number requirement, if that application is supported by other ADOs in the region which would guarantee a robust Regional ABP Program. This opens the possibility to Applicant ABP laboratories from small countries which, once approved, may offer ABP testing services to other countries in their region.

Article 4.2.2: Candidate ABP laboratory

It has been clarified that the decision of the WADA Executive Committee on whether an Applicant ABP laboratory will be granted WADA Candidate ABP laboratory status shall be provided to the Applicant ABP laboratory in writing.

Article 4.2.2.1: Candidate ABP laboratory Administrative and Technical Capabilities

The sources of laboratory funding (list of laboratory sponsors) have been included as part of the questionnaire to be completed by the Candidate ABP laboratory.

Article 4.2.2.5: Obtaining ISO/IEC 17025 or ISO 15189 Accreditation

Reference is made to the AB being a full member of the Global Accreditation Cooperation and a signatory to the MRA of the Global Accreditation Cooperation.

4.2.3: ABP Laboratory

In addition to minor editorial changes in the order of the subarticles in this Article, the following modifications were included with respect to the first draft:

Article 4.2.3.2: Maintaining ABP Laboratory Status

The requirement for the ABP laboratory to maintain up-to-date prices for blood ABP analytical services in ADAMS has been removed. In addition, the support to ADO activities has been summarized into cooperating with ADOs in support of their Results Management activities (which include administrative and legal processes linked to anti-doping rule violations).

Article 4.3: Laboratory Accreditation Requirements for Major Events

In this Article, the ISL Drafting Team wished to emphasize the importance of obtaining a written agreement between the Major Event Organization (MEO) and the laboratory with respect to Analytical Testing requirements for the Major Event, including the Test Distribution Plan (expected number of urine, blood, ABP and DBS Samples to be analyzed, Analytical Testing menus to be applied, etc.) and test result turnaround times. Such an agreement shall be reached sufficiently ahead of the Major Event (e.g., at least six (6) months before the Olympic and Paralympic Games, and at least three (3) months for other Major Events).

Article 4.3.1.1: Participation in WADA Assessment(s)

It has been clarified that a first WADA assessment of a laboratory in preparation for a Major Event should be conducted no later than three (3) months before the scheduled start of the Analytical Testing for the Major Event (no later than six (6) months before the Olympic and Paralympic Games).

Furthermore, the laboratory shall complete at least one (1) stress by the time the laboratory is in its final configuration for the Major Event, and no later than two (2) months before the start of testing or the Major Event.

It has been further clarified that 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.

Furthermore, it has also been added that WADA will inform the Testing Authority/MEO of any identified Major Nonconformity (MNC) which represents a serious risk in the laboratory's ability to conduct the required Analytical Testing menu for the Major Event.

Article 4.3.1.2: Participation in the WADA EQAS

In this Article, it has been clarified that the submission by WADA of double-blind EQAS samples for evaluation of laboratories while testing during a Major Event shall be at the request and at the expense of the MEO, and that the MEO's request to WADA for 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.

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

Changes from the First Draft

Article 5.2: Resource Requirements

The title of this Article has been changed from "Structural and Resource Requirements" to "Resource Requirements" in line with the ISO/IEC 17025.

Article 5.2.2.1: Laboratory Director

This Article has been slightly modified to better describe the qualification requirements of a Laboratory Director.

Article 5.2.2.3: Laboratory Responsible(s) for R&D Activities

NEW ADDITION

This is a new Article, which lists the qualification requirements for the person(s) responsible for the laboratory's R&D activities.

Article 5.2.3.1: Laboratory Facilities

The performance of a risk assessment has been added to the requirement to have a policy for the security of the laboratory's facilities, equipment, and systems against unauthorized access.

Article 5.2.3.5: Control and Security of Electronic Data and Information

The requirements in this Article have been further clarified to include the implementation of 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.

Article 5.2.5.2: Reference Collections

An important modification has been included to this Article, which is that past doping control Samples should not be used as Reference Collections unless there are exceptional circumstances (for example, the worldwide unavailability of Reference Materials) and the Sample is used in accordance with the requirements established in Article 8.2.1. In addition, the identity of the Analyte in the Sample shall have been unequivocally established by comparison to a Reference Material or a well-characterized Reference Collection of known origin.

Article 5.2.6: Externally Provided Analytical Services

A comment to this Article has been added to clarify that the subcontracting of ABP blood analyses to another laboratory or ABP laboratory is not a recommended practice due to the limited time requirements for such analysis.

In addition, the two following modifications have been made to this Article to clarify laboratory responsibilities when subcontracting analyses:

- 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; and
- When the request for external analysis is due to a laboratory's inability to apply a mandatory Analytical Testing Procedure (see TD ATP), without informing the Testing Authority in advance of this lack of analytical capacity, 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.

Article 5.3.1: Reception, Registration and Handling of Samples

A new requirement has been added for laboratories to identify the Samples with laboratory internal Sample codes, which provide Sample traceability to the collection document or other external chain of custody information.

Article 5.3.2: Acceptance of Samples for Analysis

It has been clarified that, except as provided in this Article, urine, blood or blood ABP Samples from a Signatory shall not be accepted by a laboratory for the sole purpose of long-term storage or for later analysis without first being subject to an Analytical Testing Procedure.

As an exception, DBS Samples collected with urine Samples during the same Sample Collection Session may be put directly in storage (without an initial analysis), provided that the Testing Authority has requested the laboratory to do so in advance. A comment has been added to clarify that the stored DBS Sample may not be used for any other purpose than Analytical Testing unless the Testing Authority has notified the laboratory, in writing, that the Sample may be discarded or used for secondary purposes (in accordance with Article 5.3.8).The proposal in the first draft to request the Athlete's consent for the DBS Sample storage without analysis has been removed from the second draft.

Furthermore, it has been clarified that when a laboratory combines different Samples, collected from the same Athlete during a single Sample Collection Session, 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.

Article 5.3.2.1: Samples with Irregularities

In addition to the classification of the Irregularities of Samples according to whether they are related to the Sample transportation, documentation or Sample conditions, as proposed in the first draft, this second draft incorporates an additional division of the irregularities into those that may or may not [as marked with an asterisk(*)] impact the Sample's chain of custody/unique identification or the suitability of the Sample to be analyzed with the requested Testing menu. In that regard, the laboratory may analyze Samples with irregularities marked with the asterisk (*), while reporting the irregularity in the Test Report in ADAMS. For those irregularities that may impact the Sample's chain of custody/identification or its suitability to be analyzed with the requested Testing menu, the laboratory shall seek instructions from the Testing Authority, in writing, on the performance of Analytical Testing on the Sample (unless there is a prior agreement to analyze such Samples). The Testing Authority shall inform the laboratory, in writing within seven (7) days, whether a Sample with the noted irregularity(-ies) shall be analyzed or not. In the absence of a timely reply (within seven (7) days) by the Testing Authority, the laboratory shall report the Sample as "Not Analyzed" in ADAMS. However, in cases where the Testing Authority (or WADA) requests the Sample analysis after the laboratory had reported it as Not Analyzed in ADAMS, this will be considered a Further Analysis.

Article 5.3.2.2: Sample Splitting Procedure

NEW ADDITION

A comment has been added to this Article to clarify that when the "A" or "B" Sample container has not been properly sealed or has been broken, the laboratory may decide, in consultation with the Testing Authority, to perform the Initial Testing Procedures (ITPs) on the affected Sample ("A" or "B", as applicable) and, if the analysis produces a Presumptive Adverse Analytical Finding, proceed to the splitting of the complementary, sealed Sample for the conduct of Analytical Testing, including the repeat of the ITP analyses and the performance of any relevant Confirmation Procedure.

Furthermore, it has been added that if the Testing Authority 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 Testing Authority did not reply to the laboratory's request for authorization to perform the Sample splitting procedure. In cases where the Testing

Authority (or WADA) requests the Sample splitting and analysis after the laboratory had reported it as Not Analyzed in ADAMS, this will be considered a Further Analysis.

An additional provision on the Sample splitting procedure has been added to clarify that the Athlete and/or their representative(s) has no right to attend the Analytical Testing Procedures to be performed on the first split fraction, which is considered as the "A" Sample.

Article 5.3.3: Initial Storage and Sample Aliquoting for Analysis

Article 5.3.3.2: Blood Samples

In consideration of comments received from various stakeholders following the consultation of the first draft, the prefix "venous" has been deleted from the name of this type of blood Samples, which are distinctively different from Dried Blood Spots (capillary blood). In addition, reference has been made to the recommendations of best practice of blood Sample storage provided in Laboratory Guidelines.

In addition, clarification has been provided about the steps to be followed by the laboratory when a whole blood Sample is collected for analysis in whole blood (or on the blood cellular fraction) and additional analyses on the plasma fraction (e.g., EPO) are also requested.

Footnote 7 has been included to clarify that the obtaining of Aliquot(s) from the blood Sample container by using single-use disposable pipettes or pipettes with disposable, non-reusable tips, is not applicable to the analysis of the hematological Markers of the ABP.

Footnote 8 explains the difference between a serum and a plasma Sample.

Footnote 10 explains what constitutes analysis in whole blood.

Article 5.3.4.2: Sample Analysis

It has been clarified that results from analyses other than those applied to detect the presence of Prohibited Substances or Prohibited Methods shall not be reported in ADAMS, unless specifically required by WADA (for example, results of the Monitoring Program, or for reporting confounding factors of the urinary "steroid profile").

Article 5.3.4.2.2.2: "A" Confirmation Procedure

NEW ADDITION

In consideration of several comments received from various stakeholders following the consultation of the first draft, the ISL Drafting Team proposes the expansion of the list of Prohibited Substances for which the laboratory may consult the Testing Authority on the existence of an approved TUE before confirming a Presumptive Adverse Analytical Finding in the "A" Sample. The additional substances include:

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

In this regard, it has been further clarified that if the laboratory does not proceed with the Confirmation Procedure upon confirmation of the existence of an approved TUE by the Testing Authority, it 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 Testing Authority of the existence of an approved TUE.

Regarding the use of Aliquots for the “A” Confirmation Procedure, it has been clarified that the laboratory may repeat the “A” Confirmation Procedure 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.

Additional important modifications have been made to this Article to clarify which type of Confirmation Procedure(s) (qualitative and/or quantitative) is applied for reporting Adverse Analytical Findings for Non-Threshold Substances without MRL, Non-Threshold Substances with MRL, and Threshold Substances. It is noted that for Threshold Substances, in particular, the Confirmation Procedure includes both a qualitative (substance identification) and a quantitative analysis (quantification of concentration or another measurable analytical variable). For endogenous Threshold Substances, Adverse Analytical Finding or Atypical Finding decisions for the “A” Sample may also be based on the application of a Confirmation Procedure that establishes the exogenous or non-conclusive origin, respectively, of the Threshold Substance.

Another important change to this Article relates to the description of those circumstances, under which the laboratory may report the presence of a Non-Threshold Substance with MRL at an estimated concentration below the MRL as an Adverse Analytical Finding. This includes the written request by the ADO as part of a Results Management investigation if there are indications of “Use” of a Non-Threshold Substance with MRL that is prohibited at all times; or as applicable, to certain Non-Threshold Substances with MRL that shall be reported as an Atypical Finding if present in a Sample at an estimated concentration below the MRL (as established in a relevant Technical Document or Technical Letter, e.g., TL23, TL24).

Article 5.3.4.2.2.3: “B” Confirmation Procedure

NEW ADDITION

Following the first draft consultation, the ISL Drafting Team has proposed the addition of the following modifications to this Article:

In addition to witnessing the opening and aliquoting of the “B” Sample, the Athlete and/or one (1) representative may also have the reasonable opportunity to observe other steps of the “B” Confirmation Procedure. However, this shall be done upon request and following the approval by the Laboratory Director (or designated Person), and with a strict respect of the new requirements as established in this Article.

The number of non-laboratory Persons that shall be authorized to attend the “B” Confirmation Procedure has been reduced by removing the participation of Persons that are not related to the Athlete; not related to the ADO with Results Management responsibilities (e.g., NADO, International Federation); or not related to WADA (e.g., in the case of Independent Observers missions during Major Events). This Article also excludes from participation the representatives from the National Olympic Committees and National Sport Federations.

As for the “A” Confirmation Procedure in the previous Article, this Article clarifies which type of Confirmation Procedure(s) (Qualitative and/or Quantitative) is applied for “B” confirmations of Non-Threshold Substances (with or without MRL), exogenous and endogenous Threshold Substances.

Article 5.3.4.3: Further Analysis

For a better understanding of the process and requirements for Further Analysis, this Article has been developed into different requirements for: a) Requests for Further Analysis (specifying which organizations may request a Further Analysis); b) Selection of Samples for Further Analysis (with provisions for Further Analysis on Samples that have not been reported yet, of which may have been reported as a Negative Finding, an Adverse Analytical Finding, or an Atypical Finding); c) Selection of laboratory for Further Analysis; and d) Analytical Testing Procedures for Further Analysis. Importantly, pursuant to Code Article 6.5, Further Analysis may not be applied on a Sample reported as an Adverse Analytical Finding 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.

Article 5.3.4.4: Alternative Biological Matrices

NEW ADDITION

A new provision has been added in this Article clarifying that if an analysis is to be conducted on a hair Sample as part of a Results Management process, such an analysis shall be conducted in a WADA-accredited laboratory at the expense of the requestor and after approval by the responsible Results Management Authority or WADA.

Article 5.3.5: Assuring the Validity of Analytical Results

The explicit requirement to use QC-charts for quantitative determinations (e.g., Confirmation Procedures for Threshold Substances, steroid profile and ABP Endocrine Module Marker measurements, GC/C/IRMS analyses) has been removed. Instead, QC-charts with appropriate warning and action limits shall be used to monitor method performance and inter-batch variability (where applicable).

Article 5.3.6.4: Reporting Test Results

NEW ADDITION

The ISL Drafting Team has proposed important modification to this Article, including:

- The inclusion of footnote 23 to explain situations that justify a partial submission of Test Results.
- Reporting Timelines, where clarification has been provided on the acceptable reasons and course of action to follow when the laboratory cannot report Test Results in ADAMS within the recommended twenty (20) days deadline. In addition, it is recommended ("should") that, to the extent possible, any agreed extension to the "A" Sample reporting deadline should not surpass forty-five (45) days from the date of reception of the Sample by the laboratory.
- Furthermore, an important new provision has been added, in line with the revised IST, for the expedited analysis and reporting of Samples 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. When the analysis of Major Event Samples is prioritized, the laboratory shall inform their other customers, so that they can agree to a delayed analysis or decide to send the Samples to another laboratory(-ies).
- It has been established, in line with the TD BAR, that the reporting of ABP blood results should occur in ADAMS within three (3) days of receipt of the Sample.
- Finally, it has been established that WADA shall monitor laboratory reporting times on a regular basis (e.g., quarterly). If a Laboratory's reporting delays are considered extensive (i.e., more than 30% of Samples are not reported within recommended period without a valid reason, as determined by WADA), the laboratory will be requested to provide a Corrective Action Report (CAR) to remedy the situation. If the delays in reporting are not satisfactorily resolved, then the laboratory will be assigned penalty points as per the Points Scale Table established in the TD PERF.

Article 5.3.6.4.1: Reporting Requirements

It has been clarified that, **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).

Furthermore, the comment on reporting findings associated with an approved TUE as a Negative Finding has been removed, since this is dealt with in Article 5.3.4.2.2.2 - "A" Confirmation Procedure.

Article 5.3.6.4.1.1: Test Report for Non-Threshold Substances

A comment has been added to this Article to clarify that if the reporting of the estimated concentration of a Non-Threshold Substance subject to an MRL (which is reported as an Adverse Analytical Finding or Atypical Finding) has been previously agreed with the Testing Authority, then the laboratory shall report the estimated concentration in the comments section of the Test Report in ADAMS (and in the Laboratory Documentation Package (LDOC), if requested). Otherwise, if the request for reporting the estimated concentration is made after the reporting of the Adverse Analytical Finding or Atypical Finding in ADAMS, the laboratory shall report the estimated concentration in writing, and in the LDOC (if requested).

A further comment has been added to clarify that, 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.

Article 5.3.7.1: Minimum Storage of Samples

Several of the footnotes below Table 1 in the first draft have been removed and transferred into the main text of the Article, including:

- If the "B" Sample Confirmation Procedure 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 Confirmation Procedure 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; and
- The laboratory shall contact and inform the relevant Testing Authority and Results Management Authority (if different) when reaching the applicable minimum storage period before disposing of any Samples with an Adverse Analytical Finding or Atypical Finding.

Following the feedback of stakeholders during the consultation of the first draft, the ISL Drafting Team decided to revert the minimum storage period of urine Samples with Negative results from six (6) months to three (3) months. In contrast, the minimum storage time for DBS Samples, irrespective of whether they have been analyzed or not, or of the analytical result, shall be six (6) months.

In addition, for clarification:

Footnote 1 under the Table: The storage conditions established in Table 1 are of a general nature. However, specific Sample storage conditions for some Test Methods or substances may be provided in Technical Document(s) or Technical Letter(s).

Article 5.3.7.2: Long-term Storage of Samples

It has been clarified that when Samples are to be transported for storage at a location outside the secured area of the laboratory, the laboratory shall secure the "A" Sample(s) to be shipped either by resealing the individual "A" Sample container(s) or by sealing the box in which the Sample(s) are shipped but only if the storage location 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.

It has also been clarified that Sample(s) may also be transported for long-term storage to a secure Sample storage facility, which is under the responsibility of the ADO that has ownership over the Samples, or under the responsibility of a Delegated Third Party designated by the ADO for the storage of the Samples (while the ADO retains ownership of the Samples).

Article 5.4: Management Requirements

A footnote 27 has been added to clarify that while Articles 5.3.9, 5.3.10 and 5.4 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).

Article 5.4.3: Document Control

A recommendation is provided for laboratories to also consider implementing the guidance of best practice provided in laboratory Guidelines and Technical Notes in their Management Systems and Standard Operating Procedures (SOPs).

Article 5.4.5: Cooperation with Customers and with WADA

NEW ADDITION

The ISL Drafting Team has included the following provision on ensuring laboratory responsiveness to WADA:

- Report to WADA any disruption in the application of mandatory Analytical Testing Procedures (see 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.

In addition, the ISL Drafting Team has accepted the following two proposals from stakeholders on the provision of Expert Opinions by Laboratories, which have been added to this Article:

- The Laboratory may refuse to provide the requested expertise, if it falls outside its competence, knowledge or experience; and
- Any expert opinion provided by the laboratory shall be in accordance with ISO/IEC 17025 requirements.

Section 6.0: WADA Laboratory and ABP Laboratory Monitoring and Performance Evaluation Activities

Changes from the First Draft

Most of the proposed changes to this Article, as indicated in the first draft, remain unamended, with some minor modifications. The content in this Article regarding the EQAS and WADA Laboratory performance evaluation activities is expanded in the associated TD EQAS and TD PERF, respectively, which are being consulted together with the second draft of the ISL 2027 and shall also become effective on 1 January 2027.

Article 6.1.2.2: Assessment Requirements

It has been clarified that, “for announced assessments”, WADA shall inform the laboratory or ABP laboratory, in advance, of the WADA Assessment Team composition, as well as the invited Accreditation Body observers (if applicable).

Article 6.1.3: Removal of Samples by WADA

It has been added that unless there are exceptional circumstances (as determined by WADA), WADA shall notify the Testing Authority of the removal of Samples, and the Testing Authority shall retain ownership of the Sample(s) as per Article 10.2.1 of the International Standard for Testing (IST).

Article 6.2: Evaluation of Laboratory Nonconformities

It has been added that, where applicable, Laboratories should also consider implementing remedial actions to address deviations from recommendations of best practice incorporated in Laboratory Guidelines or Technical Notes.

Section 7.0: Laboratory and ABP Laboratory Disciplinary Procedures

Changes from the First Draft

As for Article 7.0, most of the proposed changes to this Article, as indicated in the first draft, remain unamended, with the following minor modifications.

Article 7.1.1.1: Laboratory Noncompliances that May Lead Leading to ATR or Suspension of WADA Accreditation

In this Article, the noncompliance related to serious and repeated delays in reporting test results has been expanded to clarify that this includes frequent significant delays in meeting the recommended twenty (20) days reporting deadline without informing the responsible Testing Authorities or based on invalid reasons such as noncompliances with the implementation of mandatory requirements of the ISL, TDs, or TLs.

Article 7.1.1.3: Cessation of Analytical Testing

The terms “Immediate Provisional Suspension” or “Immediate Provisional ATR” have been changed for “Cessation of Analytical Testing”. In addition, it has been clarified that if WADA decides to send extra EQAS samples and/or perform an assessment of the laboratory before the laboratory can resume Analytical Testing, this shall be at the laboratory’s expense.

Article 7.1.2: Revocation of WADA Accreditation

A comment has been added to clarify that Lab EAG recommendations for Revocation of a laboratory’s WADA-accreditation are made in consideration of the number of false Adverse Analytical Findings and/or False Negative Findings reported by the laboratory, irrespective of the total number of penalty points accumulated during this period (i.e., after consideration of any applicable penalty point deductions), as well as to whether the laboratory has satisfactorily corrected the noncompliances.

Article 7.1.2.2: Revocation Procedures - Laboratory Not Under ATR or Suspension

If has been added that, when the Lab EAG withdraws a recommendation for Revocation, WADA nevertheless reserves the right to send extra EQAS samples and/or perform an assessment of the laboratory before the laboratory can resume Analytical Testing, and this shall be at the laboratory’s expense.

Article 7.2: Consequences of Suspended or Revoked Accreditation or ATR

Article 7.2.3: Revocation of WADA Accreditation

An explanatory footnote (footnote 31) has been included explaining the responsibilities of a revoked laboratory for the transfer of Samples to a laboratory(-ies), chosen by the Testing Authority, within thirty (30) days of being notified of the Revocation decision.

Article 7.5.1: Reinstatement of Suspended Accreditation or Lifting of ATR

It has been added that, as a condition for reinstatement of WADA-accreditation, WADA may require the analysis of additional EQAS samples and/or may conduct a laboratory assessment, at any time and at the expense of the laboratory, to evaluate the laboratory's status.

Section 8.0: Code of Ethics for Laboratories and ABP Laboratories

Following the review of stakeholder comments, the proposed changes to this Section, as indicated in the first draft, remain unamended.

PART THREE: ISL ANNEX

ISL ANNEX A – PROCEDURAL RULES FOR THE DISCIPLINARY COMMITTEE OF THE ISL

Following the review of stakeholder comments, the proposed changes to this Section, as indicated in the first draft, remain unamended.
