2027 CODE & IS UPDATE PROCESS

Final Draft: Summary of Major Changes

International Standard for Laboratories

Executive Summary

Following the careful review and consideration of stakeholder comments provided during the Third Consultation Phase and through consultations with the anti-doping community during the Final Drafting Phase, the International Standard for Laboratories (ISL) Drafting Team has proposed further key changes in a final draft of the 2027 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 final draft of the 2027 ISL, which predominantly build on those proposed in the second draft of the 2027 ISL as summarized in the corresponding second draft Summary of Major Changes.

It is to be noted that any new changes in the final draft of the 2027 ISL, which do not otherwise stem from or build on those changes indicated in the second 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:

- The drafts of four (4) new ISL Technical Documents (ISL TDs) were circulated for stakeholders' comments together with the second draft of the 2027 ISL. Following this consultation, the comments received were discussed with the respective drafting teams and the WADA Laboratory Expert Advisory Group (Lab EAG), and where appropriate, changes have been introduced into the final ISL TD drafts. These new ISL TDs will be presented for approval by the WADA Executive Committee in December 2025 and shall become effective at the same time as the 2027 ISL on 1 January 2027:
  - Method Validation Requirements (ISL TD VAL);
  - External Quality Assessment Scheme (ISL TD EQAS);
  - Laboratory Performance Evaluation (ISL TD PERF); and
  - Analytical Testing Procedures (ISL TD ATP).

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 Final Drafting Phase:

- The section on Definitions (from the Code, ISL and other International Standards such as the IST and ISRM) has been moved from Article 3.0 into Appendix I at the end of the document to harmonize the document's format and structure with the Code and other International Standards. Additional clarification has also been provided to clearly distinguish between mandatory requirements and recommendations in the document.
- The title of all TDs now starts with ISL (e.g., ISL TD DL) to indicate that these TDs are an integral part of the ISL.

- Several additional ISL TDs, most of them new, are now cited in the ISL and therefore mentioned in article 3.1, including the ISL TD APMU, ISL TD BSM, ISL TD ENDO, ISL TD HBT, ISL TD MRL and ISL TD USM (see further details below).
- Considering recent developments in the international Laboratory accreditation system, reference to the International Laboratory Accreditation Cooperation (ILAC) has been tentatively replaced by the Global Accreditation Cooperation Inc. If the Accreditation Body is not a full member of this new organization, then it shall be a full member of one of the approved and recognized Regional Cooperation Bodies, i.e., African Accreditation Cooperation (AFRAC), Asia Pacific Accreditation Cooperation Inc. (APAC), Arab Accreditation Cooperation (ARAC), European co-operation for Accreditation (EA), Inter American Accreditation Cooperation (IAAC), or Southern African Development Community Cooperation in Accreditation (SADCA).
- Since newly implemented modules of the Athlete Biological Passport (ABP) also include the analysis of blood Markers (Endocrine Module, Blood Steroids Module), reference to blood Markers of the ABP previously used to refer to the Hematological Module has now been replaced by hematological Markers of the ABP. Similarly, Blood ABP Samples (collected as part of the Hematological Module) are now called “Whole Blood Samples for Analysis of the Hematological Markers of the ABP”.
- It has been clarified that the Results Management Authority (and not the Testing Authority, if different) is responsible for any aspects related to the results management process, including, for example, the requests of Laboratory Documentation Packages or Certificates of Analysis, or for the conduct of “B” confirmation analyses.
- A better description is provided of the procedure (to follow by the Laboratory and the Testing Authority) when DBS (Dried Blood Spot) Samples are collected with urine Samples during the same Sample Collection Session from the same Athlete and put into storage without being subject to an initial analysis. Several Anti-Doping Organizations (ADOs) had requested that the collection of DBS Samples alone (without urine) for storage without initial analysis be permitted. However, the ISL Drafting Team, in consultation with the Code and IST Drafting Teams, have decided that this shall not be allowed because it risks the non-detection of a potential Adverse Analytical Finding (AAF) in a collected Sample, with the negative consequence that a doped athlete could be permitted to participate in competitions.
- For testing at a Major Event, in addition to the expected request from the Major Event Organization (or responsible Testing Authority), it has been included that WADA may also, at its sole discretion, submit double-blind EQAS samples for Laboratory evaluation during Major Event testing programs.
- It has been also clarified that the Results Management Authority 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” analysis is to be conducted. However, if the Laboratory does not receive instructions to conduct the “B” analysis or to transfer the “B” Sample to long-term storage within the minimum applicable Sample storage time from the Results Management Authority, then the Laboratory shall inform WADA and transfer the “A” and “B” Samples into long-term storage. The ADO shall bear the costs for the extended Sample storage.
- When a Sample is collected from an Athlete within twenty (20) days prior to the Athlete’s first competition at an Olympic or Paralympic Games, and the Laboratory is unable to meet the Testing Authority’s request for prioritized analysis, it shall inform the Testing Authority as soon as possible so that the Testing Authority can contact an alternative Laboratory(-ies) to conduct the prioritized analysis of the Samples.
- Several further clarifications have been made regarding the reporting of results for Non-Threshold Substances, including:
    - The Results Management Authority may request (in writing) the estimated concentration(s) of the Analyte(s) of the Non-Threshold Substance reported in the Sample, whether the Non-Threshold Substance is subject to a Minium Reporting Level (MRL) or not.

- The Minimum Required Performance Level (MRPL) is not a reporting requirement for a Non-Threshold Substance without an MRL and, therefore, the Laboratory may report the presence of a Non-Threshold Substance without an MRL at an estimated concentration below the MRPL (or below the validated Limit of Detection) if the Analyte(s) of the Non-Threshold Substance is identified in the "A" Sample in accordance with established criteria.
- Under certain circumstances, the Laboratory may report the presence of a Non-Threshold Substance with an MRL if it is identified in a Sample at an estimated level below the MRL. Further instructions on this topic will be provided in the new ISL TD MRL (currently in preparation), which will become effective at the same time as the 2027 ISL.

– The Testing Authority or the Results Management Authority (if different), or WADA, is responsible for contacting the Laboratory to request Long Term Storage (e.g., Sample storage beyond the applicable minimum storage period).

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

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

Article 1.0: Introduction and Scope

Changes from the Second Draft

Article 1.1.2 ISL Technical Documents

NEW ADDITION

It has been clarified that time-sensitive or low-impact editorial revisions of ISL TDs, while not requiring stakeholder consultation, shall nevertheless be approved by the Lab EAG before presentation to the WADA Executive Committee for approval.

Article 1.1.3 Technical Letters

NEW ADDITION

It has been clarified that time-sensitive or low-impact editorial revisions of Technical Letters (TL), while not needing stakeholder consultation, shall nevertheless be approved by the Lab EAG before presentation to the WADA Executive Committee for approval.

In addition, similarly to TDs, it has been clarified that if an approved ISL TL does not become effective immediately, its implementation may occur prior to the effective date and shall occur no later than that effective date. Furthermore, where a newly approved ISL TL works to the benefit of the Athlete, it shall be applied to the analysis of Samples as soon as it is approved by the WADA Executive Committee and published on WADA's website. Conversely, if the application of the new ISL TL would lead to an increased likelihood of reporting an AAF (e.g., reduction of an MRL for a Non-Threshold Substance), then the new ISL TL requirements shall not be applied to Samples collected before the effective date of the ISL TL.

Article 3.0: Terms and Definitions

Changes from the Second Draft

Articles 3.1 - 3.4 regarding Definitions from the Code, ISL and other International Standards (IST, ISRM) have been moved from Article 3.0 into Appendix I at the end of the document for consistency with the formatting and structure of the Code. Therefore, the name of this Article 3.0 has been changed to "**ISL Technical Documents and Interpretations**"

Article 3.1: Technical Documents cited in this version of the ISL

NEW ADDITION

Several ISL TDs were added to the list of TDs cited in the ISL:

- ISL TD APMU – Athlete Passport Management Unit Requirements and Procedures.
- ISL TD BSM – Analytical and Reporting Requirements for the Blood Markers of the Steroidal Module of the Athlete Biological Passport.
    - This is a new ISL TD, currently in preparation, which will replace the existing Laboratory Guidelines and will become effective at the same time as the 2027 ISL.
- ISL TD ENDO - Analytical and Reporting Requirements for the Blood Markers of the Endocrine Module of the Athlete Biological Passport.
    - This is a new ISL TD, currently in preparation, which will replace the existing Laboratory Guidelines and will become effective at the same time as the 2027 ISL.
- ISL TD GD – Detection of Gene Doping
    - This is a new ISL TD, currently in preparation, which will replace the existing Laboratory Guidelines on Gene Doping Detection based on Polymerase Chain Reaction.
- ISL TD HBT - Detection of Homologous Blood Transfusion (HBT) by Flow Cytometry.
    - This is a new ISL TD which was approved by the Executive Committee in September 2025, and will become effective on 1 January 2026.
- ISL TD MRL: Minimum Reporting Levels applied in *Doping Control*.
    - This is a new ISL TD, currently in preparation, which will be split from the current TD MRPL to specifically target the analytical and reporting requirements for Non-Threshold Substances subject to an MRL. It will become effective at the same time as the 2027 ISL.
- ISL TD USM – Analytical and Reporting Requirements for the Urinary Markers of the Steroidal Module of the Athlete Biological Passport
    - This is a new ISL TD, in preparation, which will replace the current TD EAAS and will become effective at the same time as the 2027 ISL.

In addition, the names of the following ISL TDs have been modified from their current versions:

- ISL TD DL: Decision Limits for the Confirmatory Quantification of Exogenous Threshold Substances
- ISL TD MRPL: Minimum Required Performance Levels for Non-Threshold Substances
- ISL TD NA: Harmonization of Analysis and Reporting of 19-Norsteroids

Article 3.2: Interpretation

NEW ADDITION

It has been clarified that defined terms from the Code and International Standards that are used in the ISL are found in Appendix I. In addition, the terms "May" and "Can" have been removed

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

Article 4.0: Process and Requirements for WADA Laboratory Accreditation, ABP Laboratory Approval and Laboratory Accreditation for Major Events

Changes from the Second Draft

Article 4.1.1.2: Submit Initial Application Form

The specific requirement that the National Anti-Doping Program, in an applicant Laboratory's host country, shall collect at least 3,000 Samples per year, of which at least 2,500 shall be urine Samples, has been removed, since this minimum number of Samples shall be met collectively by all ADOs confirming to provide Samples to the Laboratory, as established in Article 4.1.1.3. This requirement has been removed considering that it could otherwise jeopardize the establishment of WADA-accredited Laboratories in small countries from underserved regions, which could offer anti-doping testing services in their region.

Article 4.1.1.3: Provision of Letters of Support

For better clarity, it has been established that the official letter(s) of support from ADOs and/or Delegated Third Parties (DTPs) shall collectively guarantee that their Sample collection activities include the collection of at least 3,000 Samples (including urine, whole blood, ABP blood, and DBS Samples) per year, of which at least 2,500 shall be urine Samples.

NEW ADDITION

A new footnote (footnote 4) has been added to explain that whole blood Samples may be venous or liquid capillary blood, and that an 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.

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

Reference is made to the Accreditation Body being a full member of the new Global Accreditation Cooperation Inc. (which replaces the ILAC) and a signatory to the Mutual Recognition Arrangement (MRA) of the Global Accreditation Cooperation Inc., with the following clarifications:

NEW ADDITION

If a Laboratory's Accreditation Body is not a full member of Global Accreditation Cooperation Inc., then it shall be a full member of one of the approved and recognized Regional Cooperation Bodies, i.e., African Accreditation Cooperation (AFRAC), Asia Pacific Accreditation Cooperation Inc. (APAC), Arab Accreditation Cooperation (ARAC), European co-operation for Accreditation (EA), Inter American Accreditation Cooperation (IAAC), or Southern African Development Community Cooperation in Accreditation (SADCA).

The reason for this change is that some national Accreditation Bodies in charge of the ISO/IEC 17025 accreditation of WADA Laboratories may opt out of the Global Accreditation Cooperation Inc. but would still maintain their Regional Cooperation Body membership. The Global Accreditation Cooperation Inc. is expected

to become effective in 2026, and since, unfortunately, its full membership composition is not yet known, this new provision in the ISL addresses the risk that some national Accreditation Bodies may not become members of the Global Accreditation Cooperation Inc.

Article 4.1.4.2.4: Maintain ISO/IEC 17025 Accreditation

Similarly to Article 4.1.3.9 above, which is applicable to Probationary Laboratories, in this Article 4.1.4.2.4, which is applicable to accredited Laboratories, a clarification is made that if the Accreditation Body is not a full member of Global Accreditation Cooperation Inc., then it shall be full member of one of the approved and recognized Regional Cooperation Bodies, i.e., AFRAC, APAC, ARAC, EA, IAAC, SADCA.

Furthermore, footnote 5 has been updated to reflect the new title of the "TECH-1-007 Guidelines for Harmonization of Scopes of ISO/IEC 17025 Accreditation of WADA Anti-doping Laboratories", which is due to the transition of ILAC to the Global Accreditation Cooperation Inc. as an accreditation organization.

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

Once more, it has been clarified that if the Accreditation Body is not a full member of the Global Accreditation Cooperation Inc., then it shall be full member of one of the approved and recognized Regional Cooperation Bodies, i.e., AFRAC, APAC, ARAC, EA, IAAC, or SADCA.

Article 4.2: WADA ABP Laboratory Approval

Article 4.2.1.2: Submit Initial Application Form

The main change to this Article, in comparison to the second draft, is the removal of the requirement for the National Anti-Doping Program, of the applicant ABP Laboratory's host country, to collect at least 300 blood Samples for analysis of the hematological Markers of the ABP since this minimum number of blood Samples shall be met collectively by all ADOs confirming to provide blood Samples to the applicant ABP Laboratory, as established in Article 4.2.1.3. This requirement has been removed considering that it could otherwise jeopardize the establishment of ABP Laboratories in small countries from underserved regions, which could offer anti-doping testing services in their region.

Article 4.2.1.3: Provision of Letter(s) of Support

For additional clarity, it has been established that the official letter(s) of support from ADOs and/or DTPs shall guarantee that, collectively, their Sample collection activities include the collection of at least 300 blood Samples for the analysis of the hematological Markers of the ABP per year.

Article 4.2.2.1: Candidate ABP Laboratory Administrative and Technical Capabilities

NEW ADDITION

A description has been added of the process to ensure that Samples are processed and analyzed separately from clinical or other test samples, where applicable. This has been included to facilitate the chain of custody of doping control Samples and minimize the possibility of Sample contamination.

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

It has been clarified that if the Accreditation Body is not a full member of Global Accreditation Cooperation Inc., then it shall be full member of one of the approved and recognized Regional Cooperation Bodies, i.e., AFRAC, APAC, ARAC, EA, IAAC, or SADCA.

Article 4.3: Laboratory Accreditation Requirements for Major Events

NEW ADDITION

In this Article, the ISL Drafting Team considered it important to clarify that the Laboratory shall advise WADA when it becomes aware that it will be providing Analytical Testing services for a Major Event, so that WADA may consider whether a Major Event-specific Laboratory monitoring schedule needs to be implemented.

Article 4.3.1.2: Participation in the WADA External Quality Assessment Scheme

NEW ADDITION

In this Article, it is included that, in addition to the request from the Major Event Organization (or responsible Testing Authority), WADA may also, at its sole discretion, submit double-blind EQAS samples for evaluation of the Laboratory(-ies) while testing during a Major Event.

Article 4.3.2: Major Event Analytical Testing in "Satellite" Laboratory Facilities

Article 4.3.2.1: Participating in WADA Assessment(s)

It has been clarified that the initial WADA assessment of a Laboratory's "satellite facility" is at the Laboratory's expense.

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

Changes from the Second Draft

Article 5.2.2: Laboratory Personnel

NEW ADDITION

A reference to the Laboratory Research Manager (or qualified Person) position has been included.

Article 5.2.2.1: Laboratory Director

It has been clarified that the Laboratory Director's proficiency in English shall be, for example, at a level similar to level B2 of the European Framework of Reference for Languages (CEFR).

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

NEW ADDITION

It has been clarified that the R&D experience that is relevant to anti-doping is, for example, in the fields of forensic toxicology, analytical chemistry, or biomedical sciences.

Article 5.2.5.2: Reference Collections

An important modification has been made to this Article to clarify that past doping control Samples may not be used as Reference Collections. Consequently, the comment to this Article in the second draft of the 2027 ISL, which allowed such use under exceptional circumstances (for example, the worldwide unavailability of Reference Materials) has been removed. This does not preclude, however, the use of past doping control Samples as Quality Control Samples in accordance with the requirements for the secondary use of Samples for Quality Assurance as established in the ISL.

Article 5.3.1: Reception, Registration and Handling of Samples

NEW ADDITION

It has been clarified that the inspection of each individual Sample for irregularities includes DBS Samples that are collected with urine Samples during the same Sample Collection Session from the same Athlete and are transferred to storage without being analyzed.

Article 5.3.2: Acceptance of Samples for Analysis

An improved description is provided of the procedure the Laboratory and the Testing Authority shall follow when DBS Samples are collected with urine Samples during the same Sample Collection Session from the same Athlete and transferred to storage without being subject to an initial analysis. This procedure includes the following requirements:

- The Testing Authority shall request in advance and in writing that the Laboratory place the DBS Samples directly into storage without an initial analysis.

- The Laboratory shall report the DBS Sample as "Not Analyzed" in ADAMS and transfer the Sample to storage under appropriate conditions (preferably frozen). The Testing Authority shall be responsible for the costs associated with the registration, initial storage, and reporting of the DBS Samples by the Laboratory.

- The Testing Authority 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 Testing Authority shall inform the Laboratory of the Analytical Testing menu to be applied). The Testing Authority shall be responsible for any costs associated with an extended DBS Sample storage beyond six (6) months.

- The Laboratory shall update the ADAMS Sample record if the Sample is analyzed.

- The Laboratory may discard the Sample or use it for secondary purposes if no request is received from the Testing Authority for the long-term storage or analysis of the DBS Sample within six (6) months following Sample reception.

Article 5.3.2.1: Samples with Irregularities

A damaged transportation package has been removed from the list of Sample irregularities, since it would not affect the integrity of the Sample(s) if the Sample container(s) are intact and sealed.

In addition, for the analysis of blood Samples for the hematological Markers of the ABP, it is recommended that such analysis be conducted even for Samples 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).

NEW ADDITION

Furthermore, it has been established that when the Laboratory does not receive a timely reply (within seven (7) days) from the Testing Authority on whether a Sample with irregularity(-ies) should be analyzed or not, the Laboratory may, at its discretion, analyze the Sample (for example, if Sample substitution is suspected).

Article 5.3.3: Initial Storage and Sample Aliquoting for Analysis

Article 5.3.3.2: Whole Blood Samples

NEW ADDITION

To differentiate the different kinds of blood Samples that can be collected for analysis, blood Samples have been classified into two (2) broad categories: first, whole blood samples (collected in tubes containing an anti-coagulant (e.g., EDTA) either by venipuncture or from capillary blood vessels through puncture/incision of the skin); and second, Dried Blood Spots (DBS - capillary blood collected directly on an absorbent Sample support, e.g., untreated cellulose or polymeric material, and allowed to dry) (as per ISL Article 5.3.3.3). Explanatory footnotes have been added to provide clarity on the collection and analysis of whole blood, the obtaining of serum or plasma from whole blood and the collection of DBS Samples.

Article 5.3.4: Sample Analysis

This Article has been reorganized, with the first part now describing the requirements for the analysis of Samples, including the use of validated, Fit-for-Purpose Analytical Testing Procedures, the application of In-Competition or Out-of-Competition Analytical Testing menus as well as the additional analyses that may be conducted on Samples as part of the WADA Monitoring Program for results interpretation purposes or as requested during the Results Management process, as part of safety codes or for Quality Assurance purposes.

Article 5.3.4.1 – Selection and Validation of Analytical Testing Procedures – now follows this initial introduction to Sample Analysis.

Article 5.3.4.1: Selection and Validation of Analytical Testing Procedures

Pursuant to the reorganization of Article 5.3.4, Article 5.3.4.1 now contains all the requirements for the selection and validation of Analytical Testing Procedures, with specific sub-articles dedicated to the Initial Testing Procedures (Article 5.3.4.1.1) and Confirmation Procedures (CP) (Article 5.3.4.1.2) including “A” Confirmation Procedure (Article 5.3.4.1.3) as well as “B” Confirmation Procedure (Article 5.3.4.1.4).

Article 5.3.4.1.1: Initial Testing Procedures (ITPs)

NEW ADDITION

It has been clarified that 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.

Article 5.3.4.1.3: “A” Confirmation Procedure

Some changes have been included in this Article under point e), “A” CP for Non-Threshold Substances (with or without MRL) and f) “A” CP for Threshold Substances, to focus on the description of the type of Analytical Testing Procedures (e.g., Qualitative or Quantitative Procedures) and other requirements to be applied during the “A” confirmation analyses for these kinds of substances. The previous reporting requirements for “A” confirmation results have now been transferred to Articles 5.3.6.4.2 – Test Report for Non-Threshold Substances – and 5.3.6.4.3 – Test Report for Threshold Substances. The provision on the analytical requirements for Threshold Substances detected in the presence of diuretics or masking agents has been removed, since this will be dealt with in the revised ISL TD DL.

Article 5.3.4.1.4: "B" Confirmation Procedure

NEW ADDITION

An important modification has been made to this Article under point b), Notification of "B" CP, regarding the timing for requesting "B" confirmation analyses by the Results Management Authority. It has now been recommended that, if possible, the RMA should inform the Laboratory, in writing, within **thirty (30) days** following the reporting of an "A" Sample AAF by the Laboratory, whether the "B" analysis is to be conducted. This is particularly important for the confirmation of Analytes that risk degradation during Sample storage (e.g., ERAs, Markers of HBT).

Furthermore, it has been established that if the Laboratory does not receive instructions from the responsible Results Management Authority 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, the Laboratory shall then inform WADA and transfer the "A" and "B" Samples into long-term storage. The ADO shall bear the costs for the extended Sample storage.

In addition, under point c), Timing of "B" CP, it has been clarified that when the timing of the "B" CP is strictly fixed within a very short period and without any possible postponement for valid reasons, and the Athlete or the Athlete's representative cannot be present, the procedure shall then be conducted in the presence of an Independent Witness.

Article 5.3.4.3: Alternative Biological Matrices

The provision concerning the conduct of hair analysis in WADA-accredited Laboratories or in a WADA-approved Laboratory that has the analysis under their Scope of ISO/IEC 17025 Accreditation has been removed.The reasons for this removal include legal concerns about restricting the type of evidence that Athletes can present in their defense, considering that they have the burden of proof.

Article 5.3.6.4: Reporting Test Results

NEW ADDITION

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

- The extension of the "A" Sample results reporting timeline to twenty-five (25) days of Sample receipt if GC/C/IRMS analysis has been requested as part of the initial Analytical Testing menu.

- A clarification that, in the absence of feedback from the Testing Authority (or Results Management Authority, if different) within seven (7) days of being notified by the Laboratory of an extended reporting deadline and its reason(s), the Laboratory should assume that the extended reporting deadline has been accepted.

- The addition of the requirement to subcontract an analysis that is not within the Laboratory's Scope of ISO/IEC 17025 Accreditation as an example of a valid reason for an extension of the results reporting timeline.

- Further clarifications regarding the shorter reporting times required for specific occasions (e.g., in preparation for or during Major Events), including that such requests be made and agreed with the Laboratory and managed in ADAMS. For Olympic or Paralympic Games, the relevant Sample(s) should be prioritized by the Laboratory for expedited analysis and, where possible, results shall be reported, at the latest, seventy-two (72) hours prior to the opening ceremony of the Games or, at the latest, seventy-two (72) hours prior to the Athlete's first competition (as established in Article 4.8.3 of the International Standard for Testing (IST)).

- Where a Laboratory is unable to meet the Testing Authority's request for prioritized analysis, it shall inform the Testing Authority as soon as possible so that the Testing Authority 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 Testing Authority.

Article 5.3.6.4.1: Reporting Requirements

The comment to this Article regarding the Laboratory's policy for the provision of opinions has been removed and transferred to Article 5.4.5 c).

Article 5.3.6.4.2: Test Report for Non-Threshold Substances

The ISL Drafting Team has proposed important modifications to this Article, which now contains all reporting requirements for Non-Threshold Substances, including:

- The provision by the Laboratory of 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, upon request by the Results Management Authority or WADA in writing.

NEW ADDITION

- A clarification has been added as a comment to this Article, which notes that 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 Reference Materials or when the identification of the Analyte(s) has been based on the use of a Reference Collection(s) for which the concentration of the Analyte(s) is unknown).

- A further explanation has been provided to clarify that the MRPL is not a reporting requirement for a Non-Threshold Substance without an MRL and, 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 Limit of Detection) if an Analyte of the Non-Threshold Substance is identified in the "A" Sample in accordance with the ISL TD IDCR or other applicable ISL Technical Document or Technical Letter.

- Furthermore, the ISL Drafting Team, in consultation with the WADA Legal Affairs Department, has decided to maintain the possibility for the Laboratory to report, under certain circumstances, the presence of a Non-Threshold Substance with an MRL if identified in a Sample at an estimated concentration below the MRL. Examples of such specific circumstances will be provided in the new ISL TD MRL, which is being drafted and will become effective at the same time as the 2027 ISL (1 January 2027). A new comment has also been added to this Article to clarify that nothing shall prevent the Laboratory, upon written request by the ADO (Testing Authority or Results Management Authority, 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.

5.3.6.4.3: Test Report for Threshold Substances

NEW ADDITION

In accordance with the TD DL, this Article now includes the requirement for the Laboratory to report a result for a Threshold Substance as a Negative Finding when the Analyte(s) exceeds the Threshold value but is less than or equal to (≤) the Decision Limit (DL), with the recommendation for the Testing Authority (e.g., in the comments section of the Test Report in ADAMS) to consider this result for Target Testing purposes. In addition, a new comment has been added to this Article to clarify that nothing shall prevent the Laboratory, upon written request by the ADO (Testing Authority or Results Management Authority, if different, or WADA), from disclosing to the requesting ADO information about the presence of a Threshold Substance at a concentration below the DL.

The provision on the reporting of Threshold Substances detected in the presence of diuretics or masking agents has been removed from both 5.4.6.4.3 a) - "A" Sample Test Report - and 5.4.6.4.3 b) - "B" Sample Test Report as this will be dealt with in the revised ISL TD DL.

Article 5.3.7.1: Minimum Storage of Samples

NEW ADDITION

An important provision has been included in this Article to clarify that unless there is a prior agreement in writing with the Laboratory, the Results Management Authority (or WADA) is responsible for requesting to the Laboratory an extension of Sample storage (including those Samples reported as AAFs or Atypical Findings) beyond the applicable minimum Sample storage time. 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.

Table 1 relating to Minimum Sample Storage Periods has been modified to better represent the different Sample matrices (urine; whole blood, including whole venous or liquid capillary blood, plasma and serum; and DBS samples) and their respective minimum storage times.

Article 5.3.7.2: Long-term Storage of Samples

NEW ADDITION

It has been clarified that any extended Sample storage initiated by an ADO shall be conducted at the ADO's expense.

In addition, a comment to this Article has been included to clarify that IST Articles 10.2.3 to 10.2.5 shall be consulted when transferring the ownership of Samples to another ADO with jurisdiction over the Sample after the applicable minimum required storage periods, or when Samples have been placed under long-term storage.

Article 5.4.5: Cooperation with Customers and with WADA

NEW ADDITION

The ISL Drafting Team integrated certain stakeholder proposals on the provision of Expert Opinions by Laboratories. In this respect, the following two provisions have been added:

- Laboratory expert opinions shall be in accordance with the ISL Code of Ethics.
- A comment to point c) of this Article has been included (transferred from Article 5.3.6.4.1) regarding the Laboratory's policy for provision of opinions.

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

Changes from the Second Draft

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

Article 6.1.2.2: Assessment Requirements

It has been clarified that a 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).

Article 7.0: Laboratory and ABP Laboratory Disciplinary Procedures

Changes from the Second Draft

As for Article 7.0, most of the proposed changes to this Article, as indicated in the first and second drafts, remain unamended, apart from the following minor modification:

Article 7.2: Consequences of Suspended or Revoked Accreditation or Analytical Testing Restriction

Article 7.2.2: Suspension of WADA Accreditation

A comment to Article 7.2.2 i) clarifies that the negative impact of time on the analysis of the hematological Markers of the ABP is due to the short stability of the blood cells targeted for the analysis. Therefore, it is not normally feasible to send the whole blood ABP Samples to other Laboratory(-ies) for this analysis within an acceptable timeframe.

Article 8.0: Code of Ethics for Laboratories and ABP Laboratories

Following the review of stakeholder comments, the proposed changes to this Article, as indicated in the first and second drafts, remain unamended, except a minor editing change in Article 8.3.4 – Other Analytical Activities.

PART THREE: ISL ANNEXES AND APPENDICES

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

Following the review of stakeholder comments, the proposed changes to this Article, as indicated in the first and second drafts, remain unamended.

ISL APPENDIX I – Definitions

As previously indicated, this is a new Appendix containing the definitions from the Code and International Standards (ISL, IST and ISRM) that are cited in the ISL. This Appendix, including the content of former Articles 3.1 - 3.4, has been placed at the end of the ISL to harmonize the document's format and structure with the Code and other International Standards.

Most of the proposed definition changes remain unamended with respect to the second draft, with the following exceptions:

<u>Code Definitions</u>

- The definition of "Atypical Finding" indicates that the investigations for a final determination about the finding may also be directed by WADA.
- The definition of "International Standard" clarifies that International Standards shall include any Technical Documents and Technical Letters issued pursuant to the International Standard.

- The definition of “Technical Letter” clarifies that Technical Letters also apply to specific Laboratory or ABP Laboratory procedures.

NEW ADDITION

- There are two new Code definitions, which read as follows:
    - “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.
    - “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.

ISL Definitions

- The definition of “External Quality Assessment Scheme (EQAS)” indicates that DBS Samples are also distributed as part of the EQAS.
- The definition of “Independent Witness” clarifies that the restrictions for nominating a Person as an Independent Witness do not apply to Persons from other areas of the Laboratory’s umbrella organization (e.g., other Laboratories within a university or research institution).
- To ensure consistency with the Code definition of “Major Event Organization”, while maintaining its focus on the increased Laboratory operational requirements for a Major Event, the definition of “Major Event” has been updated as follows:
    - “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).”.
- The definition of “Measurement Uncertainty (MU)” has been updated to ensure consistency with the MU definition in the GUM-1:2023 (Guide to the Expression of Uncertainty in Measurement) and henceforth reads as follows:
    - “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.”
- The ISL definition of “Provisional Suspension” has been replaced by “Provisional Laboratory Suspension” to differentiate it from the Code definition of Provisional Suspension which is related to Consequences of anti-doping rule violations.

IST Definitions

NEW ADDITION

- The definition of “Passport Custodian” is included as per the IST 2027

ISRM Definitions

- Passport Custodian: this definition has been transferred from the ISRM to the IST 2027.