2027 CODE & IS UPDATE PROCESS

Stakeholder Consultation Phase: Summary of Major Changes

International Standard for Laboratories

Executive Summary

The International Standard for Laboratories (ISL) is a comprehensive, highly technical, and specialized World Anti-Doping Agency (WADA) International Standard that has undergone multiple rounds of revision since its first publication in August 2004.

Considering the ISL is a living document, it is subject to periodic review and constant improvements to better reflect the active dynamics of the promotion of clean sport as well as the developments in terms of both doping practices, scientific knowledge, technological improvements, as well as the day-to-day experience gained through the review of laboratory practices and the management of specific doping cases.

Accordingly, in this spirit of continuous development and improvements, and having carefully considered the comments and feedback received from stakeholders on the ISL Concept Paper and through other forums during the "First Drafting Phase" of the 2027 Code & IS Update Process, the 2027 ISL Drafting Team proposes the following major changes to be introduced in a revised 2027 ISL:

1. **Removal of important process requirements from the ISL, which would be incorporated into dedicated Technical Documents (TDs).**

   While TDs are an integral part of the ISL and therefore also constitute level-2 mandatory documents of the World Anti-Doping Program, the ISL Drafting Team considers that it is preferable to have these process requirements in TDs instead of the ISL as this will allow for greater flexibility for any future revisions of these requirements, which might need to be updated more frequently than the ISL. These new TDs will be dedicated to:

   - Method Validation Requirements (TD VAL);
   - The WADA External Quality Assessment Scheme (TD EQAS); and
   - WADA Laboratory Performance Evaluation System (TD PERF).

   The aforementioned TDs will be drafted by appointed teams (working groups) of experts, led by the WADA Science Department, and composed of selected members of the WADA Laboratory Expert Advisory Group (Lab EAG) and WADA-accredited laboratories. Stakeholders will be given the opportunity to consult and provide feedback on the proposed drafts for each TD before they are presented to the WADA Executive Committee for final approval. It is envisaged that not only will the newly approved TDs become effective at the same time as the revised ISL (or before, if needed), they will also form an integral part of the ISL and be referenced therein.

2. Restructuring of ISL Sections

The current ISL review has also included a comprehensive restructuring of the different ISL Sections to better reflect the WADA Anti-Doping Laboratory Accreditation and Athlete Biological Passport (ABP) Laboratory Approval requirements and operating standards, as well as WADA activities towards monitoring and evaluating laboratory performance, including the imposition of disciplinary sanctions to non-conforming laboratories.

Therefore, the ISL Drafting Team proposes that the revised 2027 ISL henceforth be structured as follows with several key changes to the relevant Sections (where applicable):

Part I: Introduction, Code Provisions, International Standard Provisions and Definitions and Interpretations

Section 1.0: Introduction and Scope

Section 2.0: Code Provisions

Section 3.0: Definitions and Interpretations

The ISL Drafting Team proposes the following major changes to Section 3.0:

- The review of certain Code and ISL definitions;
- The addition of a new article which lists the various TDs cited in the ISL; and
- The inclusion of a new article with detailed interpretation of various terms used in the ISL which are important when interpreting its provisions and requirements.

Part II Laboratory Accreditation and ABP Laboratory Approval Requirements and Operating Standards

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

The ISL Drafting Team proposes the following major changes to Section 4.0:

- The use of defined terms for ‘Candidate Laboratory’, ‘Probationary Laboratory’, and ‘Candidate ABP Laboratory’;
- The subdivision of this section into three (3) main articles (Article 4.1 - Laboratory Accreditation; Article 4.2 - ABP Laboratory Approval and Article 4.3 - Laboratory Accreditation for Major Events) pertaining to the different WADA processes applicable to laboratory accreditation / approval with an enhanced explanation and chronology of the necessary requirements to be fulfilled in order for a laboratory to advance through the different stages of the WADA-accreditation / ABP approval processes.
- The removal of articles not directly related to laboratory accreditation/approval processes, i.e., 2021 ISL Article 4.5 (the ‘Removal of Samples by WADA’, henceforth include in a new section (Section 6.0) on WADA laboratory monitoring activities); and 2021 ISL Articles 4.6.4 to 4.6.7 (henceforth included in a new section (Section 7.0) on laboratory disciplinary procedures); and
- Key changes to Article 4.1.4.2.9, which now merges the requirements for research & development (R&D) and the sharing of knowledge in order to better define the requirements for laboratories to implement a robust anti-doping R&D program and sharing of knowledge activities.

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

The ISL Drafting Team proposes the following major changes to Section 4.0:

- The removal of 2021 ISL Articles 5.3.5.1 and 5.3.5.2 on Method Validation for Non-Threshold and Threshold Substances, respectively (to be included in the new TD VAL);
- A better exemplification of sample irregularities to be noted upon sample reception in a laboratory;
- A better explanation of the 'Further Analysis' process;
- Enhanced clarity on sample minimum storage times depending on the sample matrix, including provisions for storage of dried blood spot (DBS) samples; and
- Improved clarity on the secondary use of samples for research or quality assurance purposes.

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

The ISL Drafting Team proposes the creation of a new Section dedicated to the principal monitoring activities of WADA-accredited laboratories (i.e., EQAS – with reference to the proposed new TD EQAS; Laboratory assessments; and Removal of Samples) as well as to the evaluation by WADA of laboratory nonconformities (with references to the proposed new TD PERF).

Section 7.0: Laboratory and ABP Laboratory Disciplinary Procedures

The ISL Drafting Team proposes the creation of a new Section, predominantly based on current 2021 ISL Article 4.6.4 ("Withdrawal of WADA Accreditation"), which describes the sanctions, disciplinary procedures, and applicable consequences to which laboratories and ABP laboratories are subjected in cases of noncompliances with the ISL and related mandatory normative documents (e.g., Technical Documents, Technical Letters). In addition, the ISL Drafting Team proposes that this Section, at Article 7.7, covers the measures to be implemented when a Laboratory reports false analytical findings during a Major Event.

Section 8.0: Code of Ethics

Considering the importance of current 2021 ISL Annex A ("Code of Ethics for Laboratories and ABP Laboratories"), the ISL Drafting Team proposes to incorporate the contents of this Annex into the main text of the ISL, i.e., in a newly proposed Section 8.0. As explained in greater detail below, only one change has been made to the wording of this section concerning this Code of Ethics.

Part III: Annexes

Considering the abovementioned major changes proposed by the ISL Drafting Team, only one Annex ("Annex A – Procedural Rules") will henceforth remain in the 2027 ISL and the changes to this Annex stem from the transfer of the Code of Ethics to Section 8.0 as well as changes to the accreditation requirements for Major Events at Article 4.3.

The following section will offer a concise article-by-article summary of the major changes that the ISL Drafting Team proposes to the ISL which have been described in the above paragraphs.

Section 1.0 – Introduction and Scope

Article 1.1.2: Technical Documents

To facilitate the understanding of the different steps towards the implementation of mandatory Technical Documents (TDs), the ISL Drafting Team proposes to subdivide this article into sub-articles a) "Approval and

Publication of TDs"; b) "Implementation of TDs"; and c) "Application of TDs". In sub-article a) it has been clarified that while a stakeholder consultation is conducted for new or revised TD drafts (whose implementation is not time sensitive), such consultations may not be required when a revised TD includes only minor or low-impact modifications (e.g., correction of typographical errors, formatting changes).

Article 1.1.3: Technical Letters

Similarly to Article 1.1.2 for TDs (see above), the ISL Drafting Team proposes to subdivide this article into sub-articles a) "Approval and Publication of Technical Letters (TLs)"; and b) "Application of TLs". A similar provision is included in sub-article a) concerning the stakeholder consultation for new or revised TLs.

Article 1.1.4: Laboratory Guidelines

It is proposed that this article also be subdivided into sub-articles a) "Approval and Publication of Laboratory Guidelines (LGs)"; and b) "Application of LGs".

Article 1.1.5: Technical Notes

It is proposed that this article be subdivided into sub-articles a) "Approval of Technical Notes (TNs)"; and b) "Application of TNs".

Article 1.3: WADA Laboratory Accreditation Framework and ABP Laboratory Approval

To reflect the revised structure of the 2027 ISL, the ISL Drafting Team proposes to correct its content as follows:

Part II:

Section 4: Requirements to obtain and maintain WADA-accreditation and WADA approval for the ABP, as well as the specific requirements to conduct Analytical Testing during Major Events

Section 5: Application of ISO/IEC 17025 to the field of Doping Control

Section 6: (**new**): WADA Laboratory and ABP Laboratory monitoring and performance evaluation activities

Section 7: (**new**): Laboratory and ABP Laboratory disciplinary procedures

Section 8: (**new**): ISL Code of Ethics

Part III: Annex A (Procedural Rules)

Section 3.0: Definitions and Interpretations

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

Applicable adjustments have been made to the following Code definitions:

- Atypical Finding
- Decision Limit
- Minimum Reporting Level

In addition, the following new Code definitions have been added:

- Quality Assurance
- Technical Letters

Article 3.3: Defined Terms from the International Standard for Laboratories

Modifications have been made to the following ISL definitions with the objective of better reflecting their scope and intent:

- ABP Laboratory*
- Analyte
- Further Analysis
- Laboratory*
- Limit of Detection (LOD)
- Limit of Identification (LOI)
- Measurement Uncertainty
- Non-Threshold Substance

* Many of the ISO/IEC 17025 (or ISO 15189, as applicable for ABP Laboratories) requirements for the analysis of doping control samples are equally applicable to both ABP Laboratories and Accredited Laboratories. Therefore, to facilitate the comprehension and interpretation of the ISL, the ISL Drafting Team has included a comment to these two definitions clarifying that when requirements apply to both Accredited Laboratories and ABP Laboratories, they will be generically referred to as “Laboratory(-ies)”. If, instead, provisions apply exclusively to either Accredited Laboratories or ABP Laboratories, the specific definition will be used as applicable.

In addition, the following new ISL definitions have been added:

- Applicant ABP Laboratory
- Applicant Laboratory
- Candidate Laboratory
- Candidate ABP Laboratory
- Probationary Laboratory

Finally, the following 2021 ISL definitions have been removed:

- Technical Letters (now a Code definition)

And the following definitions, since they shall not be used in the ISL anymore but rather incorporated into the applicable Technical Documents:

- Bias
- Corrective Action Report
- Intermediate Precision
- Repeatability
- Reproducibility

Article 3.5: Technical Documents cited in this International Standard for Laboratories

This is a new article listing all the Technical Documents cited in the 2027 ISL, for easiness of reading and referencing.

Article 3.6: Interpretation

In this article, it has been clarified that TDs and TLs associated with the ISL have the same mandatory status as the rest of the International Standard and constitute an integral part of it. In addition, interpretation guidance is given for terms used in the ISL (shall, should, may, can).

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

Article 4.1: WADA Laboratory Accreditation

Article 4.1.1.1: Expression of Interest

Article 4.1.1.1 clarifies that once WADA has been contacted with an expression of interest, the Applicant Laboratory shall be provided with information regarding the accreditation process including the initial accreditation fee.

Article 4.1.1.2: Submit Initial Application Form

Article 4.1.1.2 includes criteria that describe how the host country of an Applicant Laboratory shall demonstrate that its national anti-doping program is robust. In this regard, and in order to be eligible to host an Applicant Laboratory, the national anti-doping program shall have demonstrated, in the most recent full year, that its sample collection activities included the collection of at least 3,000 samples (e.g., urine, blood, blood ABP, and Dried Blood Spot Samples), of which at least 2,500 shall be urine samples.

Article 4.1.1.4: Provision of Business Plan

This article clarifies that the Applicant Laboratory shall provide their business plan within eight (8) weeks after WADA's request.

Article 4.1.2: Candidate Laboratory for WADA Accreditation

At Article 4.1.2, the ISL Drafting Team has adjusted the review process for an Applicant Laboratory by requiring that WADA (supported by the Lab EAG) review the application materials to assess compliance to 2027 ISL Article 4.1 requirements and issue a recommendation to the WADA Executive Committee on the granting of the Candidate Laboratory status.

Article 4.1.2.1: Payment of Initial Accreditation Fee

Article 4.1.2.1 is a new article which describes that once approved by the WADA Executive Committee, the Candidate Laboratory shall pay WADA the first part of the one-time non-refundable fee, as determined by WADA, to cover the costs related to the initial accreditation process and preparation of the EQAS samples necessary for the Pre-Probationary Test (PPT).

Article 4.1.2.2: Candidate Laboratory Administrative and Technical Capabilities

Here, the ISL Drafting Team wishes to simplify the description of the topics included in the Candidate Laboratory questionnaire since the questionnaire document contains the relevant details. This proposed simplification at Article 4.1.2.2 will also allow WADA to customize the laboratory questionnaire, as needed, to gather the relevant detailed information on the Candidate Laboratory's administrative and technical capabilities for review by WADA.

Article 4.1.2.5: Analytical Testing Procedures

Article 4.1.2.5 is a new article which advises the Candidate Laboratory to focus their efforts, at this stage, on acquiring reference materials and developing analytical testing capacity in order to analyze a defined list of prohibited substances and prohibited methods for the PPT. Moreover, the laboratory shall provide documentation to WADA demonstrating that they have completed this stage.

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

The ISL Drafting Team has sought to further clarify at Article 4.1.2.6 the timeline of the PPT and on-site assessment by stating that the Candidate Laboratory should be ready for the PPT and on-site assessment within two (2) years of being granted Candidate Laboratory status by the WADA Executive Committee.

Article 4.1.2.7: Payment of Probationary Phase Fee

Article 4.1.2.7 is a new article which states that before entering the probationary phase of accreditation, the second part of the accreditation fee shall be paid to WADA to cover the costs related to the probationary phase accreditation activities.

Article 4.1.2.8: Duration of Candidate Phase of WADA Accreditation

The ISL Drafting Team proposes a separate article, Article 4.1.2.8, that further clarifies that a laboratory can remain as a Candidate Laboratory for a maximum of three (3) years, otherwise the laboratory may have their candidate status revoked by the WADA Executive Committee.

Article 4.1.3.1: Entering the Probationary Phase of WADA Accreditation

This article seeks to clarify that the Candidate Laboratory's entry into the probationary phase of WADA accreditation is dependent on satisfactory completion of all Candidate Laboratory requirements, as determined by WADA (upon advice by the Lab EAG).

Article 4.1.3.3: Provision of Renewed Letters of Support

The ISL Drafting Team has established a new requirement at Article 4.1.3.3 whereby the Probationary Laboratory shall provide renewed letters of support from the laboratory's host organization(s) and Signatories to ensure that they continue receiving proper support to achieve WADA laboratory accreditation.

Article 4.1.3.10: WADA Accreditation Assessment - Final Accreditation Test (FAT)

The ISL Drafting Team has sought to further clarify the timeline of the FAT and on-site assessment at Article 4.1.3.10 by stating that the laboratory should satisfactorily participate in the FAT and on-site assessment within two (2) years of becoming a Probationary Laboratory. Guidance is included whereby a Probationary Laboratory is expected to have developed full capacity for the analysis of prohibited substances and prohibited methods as required from WADA-accredited laboratories. In addition, the Probationary Laboratory will have a maximum of one (1) year to correct and improve any pending nonconformity(-ies) from the FAT and on-site assessment, otherwise it may need to reapply for Candidate Laboratory status.

Article 4.1.3.11: Duration of Probationary Phase of WADA Accreditation

In this article, the ISL Drafting Team has sought to further clarify that 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) and that the failure 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.

Article 4.1.4 – WADA-Accredited Laboratory

Article 4.1.4.1: Obtaining WADA Accreditation

The ISL Drafting Team proposes a separate article to clarify that after the WADA Executive Committee grants WADA accreditation, the laboratory's WADA accreditation certificate will be issued and published.

Article 4.1.4.2 – Maintaining WADA Accreditation

Article 4.1.4.2.1: Payment of Annual Re-Accreditation Fee

Article 4.1.4.2.1 is a new article that clarifies the requirement for Accredited Laboratories to pay their annual reaccreditation fee.

Article 4.1.4.2.2: Document Compliance with the ISL Code of Ethics

In this article, the ISL Drafting Team has sought to include further clarifications on how the Accredited Laboratories shall document and maintain compliance with the ISL Code of Ethics.

Article 4.1.4.2.4: Maintain ISO/IEC 17025 Accreditation

This article includes further clarification and requirements on the inclusion of methods into the scope of accreditation. Importantly, it specifies that the inclusion of an Analytical Testing Procedure within the Laboratory's Scope of ISO/IEC 17025 Accreditation establishes that it is Fit-for-Purpose, and therefore, the Laboratory shall not be required to provide Analytical Method validation documentation or EQAS performance data in support of an analytical finding. In addition, requirements are provided on the steps laboratories must take to include new Analytical Testing Procedures and WADA-specific Analytical Testing Procedures into the scope of their accreditation before application to the analysis of samples.

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

The ISL Drafting Team proposes to combine the requirements for R&D and sharing of knowledge activities and also clarify in this article that a laboratory's management system shall define a R&D unit with a qualified individual responsible for R&D activities. Furthermore, it is proposed that this article underline the additional requirement for Accredited Laboratories to produce a R&D and sharing of knowledge activity report on a biennial basis, which will serve as the basis for WADA's assessment of the laboratory's contribution to the development of anti-doping science.

In this respect, it should be noted that the ISL Drafting Team has moved all articles under ISL 2021 Article 4.5 ("Removal of Samples by WADA") to a new Section 6.0 ("WADA Laboratory and ABP Laboratory Monitoring and Performance Evaluation Activities").

It should further be noted that the ISL Drafting Team has moved all articles under ISL 2021 Article 4.6.4 ("Withdrawal of WADA Accreditation"), 4.6.5 ("Consequences of Suspended or Revoked Accreditation or Analytical Testing Restriction"), 4.6.6 ("Reinstatement of Suspended Accreditation or Lifting of the Analytical Testing Restriction"), and 4.6.7 ("Voluntary Cessation of Laboratory Operations") to a new Section 7.0 ("Laboratory and ABP Laboratory Disciplinary Procedures").

Article 4.2: WADA ABP Laboratory Approval

As it concerns Article 4.2, the ISL Drafting Team has introduced additional criteria for the WADA ABP laboratory approval procedure, as further detailed below.

Article 4.2.1 – Applicant ABP Laboratory

Article 4.2.1.2: Submit Initial Application Form

Article 4.2.1.2 includes criteria which describe how the host country of an Applicant ABP Laboratory can demonstrate the robustness of its national anti-doping program (i.e., Test Distribution Planning (TDP), sample collection and results management activities). In order to host an Applicant ABP Laboratory, the ISL Drafting Team considers that the national anti-doping program shall have demonstrated, in the most recent full year, that its sample collection activities included at least 200 ABP samples in compliance with the International Standard for Testing (as determined by WADA).

Article 4.2.1.3: Provision of Letter(s) of Support

Article 4.2.1.3 introduces an additional requirement whereby the 'Letters of Support' for an Applicant ABP Laboratory shall include a declaration from the supporting Signatory that their relationship with the Applicant Laboratory is compliant with ISL Article 4.1.4.2.5, as it concerns the maintenance of the laboratory's independence and impartiality.

Article 4.2.1.4: Provision of Business Plan

Article 4.2.1.4 is a new article which shall require an Applicant ABP Laboratory to provide a business plan within eight (8) weeks, upon request by WADA, and which shall notably include market considerations (e.g., clients, number of samples, maintenance costs, etc.), facility, instrumental, staffing and training needs as well as long-term guarantees regarding adequate financial and human resources.

Article 4.2.2.1: Candidate ABP Laboratory Administrative and Technical Capabilities

The ISL Drafting Team has sought simplify the description of the topics included in the ABP Laboratory questionnaire in the ISL given that the ABP Laboratory questionnaire document contains the relevant details. Furthermore, as a result of the proposed wording of this article, WADA will be able to customize the ABP Laboratory questionnaire, as needed, to gather relevant detailed information on the Candidate ABP Laboratory's administrative and technical capabilities for review by WADA.

Article 4.2.2.2: Compliance with the ISL Code of Ethics

Article 4.2.2.2 includes additional details vis-à-vis the requirement for a Candidate ABP Laboratory to not conduct any anti-doping analytical testing activities for Signatories or WADA and shall not accept samples directly from individual athletes, individuals, or organizations who are acting on their behalf.

Article 4.2.2.4: Laboratory Independence and Impartiality

In this article, the ISL Drafting Team proposes to remove the description of administrative and operational independence and replace it with a reference to the appropriate 2027 ISL Article (Article 4.1.4.2.5) which details these requirements.

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

The ISL Drafting Teams proposes the addition of a new requirement at Article 4.2.2.5 whereby Accrediting Bodies (AB) granting the ISO/IEC 17025 or 15189 accreditation to a Candidate ABP Laboratory will now include an ISL-trained assessor in the Accrediting Body assessment team (similar to the laboratory accreditation process).

Article 4.2.2.6: Professional Liability Insurance Coverage

At Article 4.2.2.6, the ISL Drafting Team has proposed to reduce the professional liability risk insurance coverage required of ABP Laboratories to no less than one (1) million USD annually (currently two (2) million USD annually under the 2021 ISL) since it is considered that ABP Laboratories analyze fewer samples and carry less risk than Accredited Laboratories, notably because they analyze samples for the markers of the hematological module of the ABP only (and do not issue Adverse Analytical Findings (AAFs)).

Article 4.2.2.7: WADA On-Site Assessment for the ABP Approval

This article introduces a clarification according to which the on-site assessment of a Candidate ABP Laboratory will be conducted after it has participated in at least one (1) WADA EQAS round. This will ensure that EQAS performance data is available for the on-site assessment.

Article 4.2.2.8: Duration of Candidate ABP Approval Phase

The intention of Article 4.2.2.8 is to clarify that a Candidate ABP Laboratory shall achieve ABP approval within one (1) year, unless otherwise determined by WADA due to exceptional circumstances.

Article 4.2.3 – ABP Laboratory

Article 4.2.3.3: Maintaining ABP Laboratory Status

With regards to Article 4.2.3.3, the ISL Drafting Team proposes to clarify the additional requirements for an ABP Laboratory to maintain their ABP approval status, including (i) maintenance of the laboratory's independence and impartiality; (ii) continued payment of WADA EQAS fees; (iii) providing letters of support (if requested by WADA to ensure continued support); (iv) maintenance of an up-to-date ABP blood analysis price list in ADAMS; and (v) participation in WADA and Accrediting Body assessments as needed. A new requirement to analyze a minimum of 300 ABP samples from Signatories has also been included.

Article 4.3: Laboratory Accreditation Requirements for Major Events

The ISL Drafting Team proposes to incorporate the requirements from current 2021 ISL Annex B ("Accreditation Requirements for Major Events") into 2027 ISL Section 4.0 ("Process and Requirements for WADA Laboratory Accreditation, ABP Laboratory Approval and Laboratory Accreditation for Major Events").

Article 4.3.1: Major Event Analytical Testing in the Laboratory Facilities

The ISL Drafting Team proposes to introduce further clarifications vis-à-vis the validated methods that shall be included in a laboratory's scope of ISO/IEC 17025 accreditation prior to the start of Analytical Testing for a Major Event.

Article 4.3.1.1: Participation in WADA Assessment(s)

In this article, the ISL Drafting Team has proposed to clarify that: (i) a Major Event's TDP will also be considered by WADA to determine the number and type of assessments that will be conducted to assess the laboratory

prior to the Major Event; and (ii) the laboratory's dedicated space and security measures for the "B" Sample opening procedure shall ensure the confidentiality of the Athlete(s).

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

The ISL Drafting Team has introduced a clarification according to which the laboratory's "satellite facility" shall be established sufficiently in advance of a Major Event to allow for the timely transfer of laboratory operations and validation of test methods.

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

Article 5.2.2.1: Laboratory Director

The ISL Drafting Team has sought to further strengthen the role, responsibilities, and qualifications of a Laboratory Director to ensure adequate Laboratory operational performance, including:

- Responsibility for disseminating WADA correspondence (e.g., normative documents, instructions, guidance documentation) to the relevant laboratory staff. This is important to ensure that the relevant instructions and guidance are available to the responsible technical staff.
- The Laboratory Director should be a full-time appointment and if the Laboratory Director holds other positions, they shall not adversely impact the Director's Laboratory responsibilities.
- The Laboratory Director should have at least a B2-level proficiency in English as per the European Framework of Reference for Languages (CEFR), or similar. The ISL Drafting Team considers that this requirement is necessary for an adequate performance of a Laboratory Director's functions as part of the international anti-doping community and in accordance with the Code, the ISL, and its associated Laboratory normative documents.

Article 5.2.2.2: Laboratory Quality Management Staff

Instead of a single staff member appointed as the Laboratory Quality Manager, the ISL Drafting Team proposes that a Laboratory may either have a single staff member appointed as the Laboratory Quality Manager, or a defined Quality Management Team whose priority and functions shall be focused on quality assurance and quality control activities. This takes into consideration the heterogeneity of Laboratory organigrams and structures, while ensuring that there is an adequate level of quality assurance and quality control activities.

Article 5.2.2.3: Laboratory Certifying Scientists

Article 5.2.2.3 now includes an additional requirement for the qualification of Laboratory staff members as 'Certifying Scientists', namely, to have a thorough understanding of the Laboratory's Management System including the review, interpretation, and reporting of test results, the maintenance of Laboratory Chain of Custody records, and the proper implementation of corrective actions in response to analytical problems.

(Former) Article 5.2.2.4: Laboratory Supervisory Personnel

The ISL Drafting Team has removed this article since this qualification is not consistently applied amongst Laboratories and it is considered to be widely covered by the main positions of Laboratory Director, Quality Manager (Team), and Certifying Scientists.

Article 5.2.3 – Laboratory Facilities and Environmental Conditions

Article 5.2.3.1: Laboratory Facilities

The ISL Drafting Team has removed the requirement to have a person assigned as the security officer given that personnel security assignments vary in accordance with institutional and local policies. Importantly, however, a Laboratory must have a policy for the security of its facilities, equipment, and systems against unauthorized access.

The paragraph in this article regarding the transportation of samples for long-term storage has also been removed since it is covered in 2027 ISL Article 5.3.7.1, which concerns the long-term storage of samples.

Article 5.2.3.3: Environmental Control

The 2027 ISL clarifies that the Laboratory environmental conditions shall be in accordance with the requirements of ISO/IEC 17025 (or ISO 15189, as applicable for ABP laboratories). This would cover policies on storage and handling of controlled substances.

It has been also specified that the Laboratory policy to ensure appropriate electrical service and environmental conditions shall be based on a risk assessment.

Article 5.2.3.4: Confidentiality of Data, Information and Operations

The 2027 ISL clarifies that 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.

Article 5.2.4: Laboratory Equipment

Article 5.2.4 clarifies that the Laboratory shall operate and maintain the equipment in accordance with the requirements of ISO/IEC 17025 (or ISO 15189, as applicable for ABP Laboratories). This includes the maintenance and calibration of equipment, as well as periodic performance checks along with servicing, cleaning, and repairs.

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

This article has been expanded to cover requirements for the use of chemicals, reagents, and kits, which are currently covered at 2021 ISL Article 5.2.7. In addition, it has been clarified that the Laboratory shall maintain a record of reference standards utilized in Analytical Testing (e.g., Reference Materials, stock and working solutions, calibrators, quality control samples) including records of traceability to the original material, evaluation, and approval prior to implementation in routine operations.

Article 5.2.5.1: Reference Materials (RMs)

Article 5.2.5.1 clarifies that, where justifiable (i.e., in cases of unavailable, rare, or difficult to obtain RMs or Reference Collections), the Laboratory may consider using in-house prepared RMs (in accordance with ISO Guide 80) or extending the RM expiration date if adequate documentation exists confirming that no significant deterioration has occurred or that appropriate purification or verification of fitness-for-purpose has been performed. The process to extend the expiration date of a RM, RC, or solution shall be described in the Laboratory's Management System documentation.

Notwithstanding the above, the comment to this article specifies that such an extension of the expiration date of RMs is not permitted for RMs which are used in the confirmatory quantification of threshold substances.

Article 5.2.5.1: Reference Collections (RCs)

Considering the importance of having RCs containing substances for which RMs are not available, the ISL Drafting Team has included in this article the possibility of using past doping control samples (which are due for disposal) as RCs, so long as this use in done in accordance with the requirements of 2027 ISL Article 5.3.8.2 for the secondary use of samples for quality assurance/quality control purposes.

Article 5.2.6: Externally Provided Analytical Services

At Article 5.2.6, the ISL Drafting Team has renamed the term 'Subcontracting of Analysis' as 'Externally Provided Analytical Services', as this is in line with the terminology used in the current ISO/IEC 17025: 2017.

In addition, this article provides specific guidance regarding the transfer of aliquots and samples to the external provider of analytical services (e.g., a subcontracted laboratory), as well as the maintenance of sample chain of custody and the reporting of analytical results for the subcontracted analysis.

(Former) Article 5.2.7: Purchasing of Services and Supplies

The ISL Drafting Team has removed this article given that the elements pertaining to the use of controlled chemicals and reagents, waste disposal and environmental health, and safety policies are covered under ISO/IEC 17025 (or ISO 15189, as applicable for ABP Laboratories) requirements as referenced in 2027 ISL Article 5.2.3.3 ("Environmental Control").

Likewise, the use of chemical and reagents, including the extension of the expiration date of rare or difficult to obtain Reference Materials or Reference Collections for use in qualitative Analytical Testing Procedures is now covered in 2027 ISL Article 5.2.5 ("Metrological Traceability – Use and Control of Chemicals, Reagents and Reference Materials").

Article 5.3: Process Requirements

The ISL Drafting Team has reorganized the articles in this subsection to better represent the sample flow in the Laboratory from Reception (Article 5.3.1) through Acceptance of Samples (Article 5.3.2), Initial Storage and Aliquoting (Article 5.3.3), Analysis (Article 5.3.4), Assuring the Validity of Analytical Results (Article 5.3.5), Results Management (5.3.6), Storage of Samples (Article 5.3.7), Secondary Use or Disposal of Samples and Aliquots (Article 5.3.8), Control of Nonconformities (Article 5.3.9), and management of Complaints (Article 5.3.10).

(Former) Article 5.3.1: Reviewing of Requests, Tenders and Contracts

The ISL Drafting Team has removed this article since it is covered by the requirements of ISO/IEC 17025 (or ISO 15189, as applicable for ABP Laboratories).

Article 5.3.2: Acceptance of Samples for Analysis

The ISL Drafting Team has included the following exception for DBS samples only, which are collected with urine and/or venous blood samples in the same Sample Collection Session: Provided that the Testing Authority has requested via ADAMS and in advance that the Laboratory put the DBS samples in storage without initial analysis, and that the Athlete has consented to the collection of the DBS sample for storage and possible future analysis, the DBS sample may be stored by a Laboratory without first being subject to an Analytical Testing Procedure.

In such cases, the Laboratory shall report the DBS sample as 'Not Analyzed' in ADAMS (see 2027 ISL Article 5.3.6.4.1) until such a time that the DBS sample is analyzed, and the ADAMS sample record is updated accordingly.

Article 5.3.2.1: Samples with Irregularities

In order to facilitate the reporting of irregularities observed in samples received at the Laboratory, Article 5.3.2.1 has been expanded to provide more examples of sample irregularities caused by inadequate transportation conditions, issues with sample collection documentation, and unusual sample conditions. In addition, specific guidance is provided for the Laboratories to inform and seek instructions from the Testing Authority on the performance of Analytical Testing on samples with irregularities, as well as the ensuing feedback to be provided by the Testing Authority to the Laboratory (in writing within seven (7) days).

Article 5.3.3: Initial Storage and Sample Aliquoting for Analysis

Article 5.3.3 stems from 2021 ISL sub-article 5.3.4.2 concerning the storage and aliquoting of blood samples which has been subdivided into two new Articles, Article 5.3.3.2 ("(Venous) Blood Samples") and Article 5.3.3.3 ("Dried Blood Spot (DBS) Samples").

Article 5.3.3.2: (Venous) Blood Samples

The ISL Drafting Team has included a further requirement for samples for which Analytical Testing will only be performed on the blood serum/plasma fraction, including namely that the "B" Sample tube is transferred to freezing at -70 °C or less after the conclusion by the Laboratory of a presumptive adverse analytical finding in the "A" sample. Where needed, "B" sample plasma or serum aliquots shall be analyzed within twenty-four (24) hours after thawing, and the remaining "B" Sample shall be returned to storage at -70°C or less. All these proposed measures are implemented to minimize the risks of sample contamination or analyte degradation during "B' sample storage.

For samples for which Analytical Testing will be performed on the cellular fraction of whole blood, this article specifies that if additional analyses (e.g., EPO) are to be performed on the plasma fraction of the whole blood sample, the sample centrifugation and additional analysis shall await the completion of the analyses (including the Initial Testing Procedures (ITPs), and any applicable "A" and/or "B" Confirmation Procedures (CPs)) on the cellular components of whole blood.

Article 5.3.3.3: DBS Samples

This new article refers to the directives from the Technical Document on DBS, or other applicable Technical Document, Technical Letter or Laboratory Guidelines for DBS Sample storage and aliquoting.

Article 5.3.4 – Analysis of Samples

Article 5.3.4.1: Selection and Validation of Analytical Testing Procedures

In this article, all previous ISL requirements on method validation, revalidation, or partial reassessment of the validation process have been removed, since these details will be included in a new Technical Document on Method Validation (TD VAL). Consequently, the ISL Drafting Team has removed the requirements currently at 2021 ISL Articles 5.3.5.1 and 5.3.5.2 on the Validation of Analytical Testing Procedures for Non-Threshold Substances and Threshold Substances, respectively, as they will be included, with appropriate revisions, in the TD VAL.

Article 5.3.4.2: Sample Analysis

For additional clarity, Article 5.3.4.2 mentions that Laboratories shall employ only validated, fit-for-purpose Analytical Testing Procedures documented in the Laboratory's Management System (e.g., SOPs) to the analysis of doping control samples.

Article 5.3.4.2.2.2: "A" Confirmation Procedure

In Article 5.3.4.2.2.2 sub-article b), "Target Analytes", the ISL Drafting Team has provided further guidance on the CP(s) to be applied by Laboratories, in consultation with Testing Authorities, when more than one (1) prohibited substance, metabolite(s) or marker(s) of a prohibited substance, or marker(s) of the use of prohibited method is detected by the ITP(s). The criteria for selection of targets include, but are not limited to: (i) the existence or not of an approved TUE; (ii) the prioritization of prohibited substance(s) or prohibited method(s) that carry the longest potential period of ineligibility (non-specified substances and methods); (iii) the volumes available in the "A" and "B" Samples; and (iv) the costs of analyses (although this shall not be the main criterion for selecting which finding to confirm). The Testing Authority (or Results Management Authority) shall inform the Laboratory which finding shall be subjected to confirmation in writing within seven (7) days of being consulted by the Laboratory. In the absence of such timely information, the Laboratory shall proceed to confirm as many of the findings as reasonably possible and accordingly invoice the Testing Authority for the costs of the analyses.

In addition, comment 1 to Article 5.3.4.2.2.2 c) clarifies that the selection of substances subject to TUE enquiries by Laboratories before proceeding to confirmation analyses is based on criteria such as the prevalence of substance medical use or the non-mandatory status of the CPs for Laboratories. However, while this TUE enquiry is generally not mandatory for Laboratories, the Laboratory shall consult the Testing Authority (or Results Management Authority) about the existence of an approved TUE if the Laboratory does not have a validated CP included in its Scope of ISO/IEC 17025 Accreditation and has to subcontract the confirmation analysis to another Laboratory. In such case, the Testing Authority would have to assume the additional costs for the shipment of the sample to the subcontracted Laboratory.

Under sub-article e), " "A" Confirmation Procedure for Non-Threshold Substances", the ISL Drafting Team has clarified that the Laboratory may report an AAF for a Non-Threshold Substance with a Minimum Reporting Level (MRL) with an estimated concentration below the MRL if the Non-Threshold Substance is identified in compliance with the TD IDCR and the TD MRPL and, in addition, there are other reasons for the reporting, for example:

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

Under sub-article f) " "A" Confirmation Procedure for Threshold Substances", it has been clarified that Atypical Findings may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

Article 5.3.4.2.2.3: "B" Confirmation Procedure

Under sub-article c), "Timing of "B" Confirmation Procedure", the ISL Drafting Team has recommended that the "B" CP is performed within one (1) month of reporting the AAF for the "A" sample. This recommendation stems from the objective of minimizing the risk of target substance degradation during the "B" sample storage.

A comment to Article 5.3.4.2.2.3 j), " "B" Confirmation Procedure with Negative Results", clarifies that a failure of a "B" CP to confirm the "A" sample AAF does not necessarily mean that the "A" Sample result is incorrect. Certainly, a discrepancy between the "A" and "B" Sample results may occur, for example, in cases of substance degradation during "B" sample storage (e.g., in cases of recombinant EPO). Accordingly, this underlines the

importance that the “B” sample confirmation, if requested, be conducted as soon as possible after the “A” sample AAF is reported by the Laboratory.

Considering that for endogenous Threshold Substances the threshold has been established based on reference population statistics and already reflects the uncertainty of the measurements (and, therefore, the threshold constitutes the Decision Limit), it has been clarified, under sub-article l) “ “B” confirmation procedures for endogenous threshold substances”, that AAF decisions for the “B” sample results shall be based on a quantitative determination in the “B” sample at a level exceeding the value of the relevant Decision Limit.

Article 5.3.4.4: Alternative Biological Matrices

In this article, the ISL Drafting Team has included DBS as a blood matrix.

Article 5.3.5: Assuring the Validity of Analytical Results

Article 5.3.5 clarifies that QC-charts shall also be applied for monitoring method performance for steroid profile and ABP endocrine module marker measurements as well as GC/C/IRMS analyses.

Further, it is specified that the Laboratory’s Internal Quality Assurance Scheme (iQAS) shall be based on a risk assessment and incorporate a procedure that prevents the submission of iQAS results into ADAMS.

For Laboratory audits, it is now clarified that the conduct of an audit by Laboratory-selected external auditors (e.g., other Laboratory Directors) is considered as an internal audit.

Article 5.3.6 – Results Management

Article 5.3.6.1: Review of Results

Under sub-article c), “Request for Second Opinions”, the ISL Drafting Team has clarified that requests for second opinions are not permitted for analytical results associated with the blind or educational EQAS, unless approved or instructed by WADA. In addition, this article establishes that when the second provider is not a member of the relevant WADA Technical Working Group, they shall be at least a Certifying Scientist for the Analytical Testing Procedure and shall be approved to provide second opinions by the Laboratory Director.

Article 5.3.6.4.1.1: Test Report for Non-Threshold Substances

In this article, under sub-article a) ii., Laboratories are now required to (i.e., “shall”) report the concentrations for Non-Threshold Substances subject to an MRL, as estimated during the “A” sample confirmation, upon request by the Testing Authority, the Results Management Authority, or WADA. However, the Laboratory shall specify that the concentration was estimated by an Analytical Testing Procedure that has not been validated for quantitative purposes. The provision of such information may be relevant for results management purposes.

In turn, sub-article a) i. establishes that for Non-Threshold Substances, which are not subject to an MRL, the Laboratory is not required to report concentrations and “should” only do so if possible and upon request by the Testing Authority, the Results Management Authority, or WADA.

In contrast to the provisions for “A” Sample test reports, when reporting “B” Sample results for Non-Threshold Substances, the Laboratory is not required to estimate nor report the concentration of the Non-Threshold Substance in the “B” sample.

Article 5.3.6.4.1.2: Test Report for Threshold Substances

Similarly to Non-Threshold Substances, this article stipulates the Laboratory is **not** required to estimate/quantify nor report the concentration of an **exogenous** Threshold Substance in the "B" Sample.

For **endogenous** Threshold Substances, the Laboratory shall establish that the prohibited substance or its metabolite(s) or marker(s) is present at a level of measured analytical values which is greater than the Decision Limit (which in this case constitutes the threshold: see modifications to 2027 ISL Article 5.3.4.2.2.3 above).

Article 5.3.7: Storage of Samples

The ISL Drafting Team has substantially simplified this article by including a summary of sample storage requirements [a) to e)] that are applicable to all sample matrices. In addition, minimum storage times for different matrices (urine, whole blood, plasma, serum, and DBS) have been summarized in Table 1, with the following main changes:

- The minimum storage time for urine samples with negative findings has been increased from three (3) to six (6) months. This would allow more time for additional analyses which may be performed on samples associated with atypical passport findings.
- Minimum storage times have been established for DBS samples (same as for plasma/serum).

Article 5.3.8.2: Secondary use of Samples and Aliquots for Research and Quality Assurance Purposes

This article aligns the requirements of the secondary use of doping control samples and aliquots for research or quality assurance purposes with Code Articles 6.3 and 19, by establishing that direct identifiers be removed or irreversibly altered to prevent samples and analytical data from being traced back to a particular person. Once more, it is stressed that athlete consent must be obtained before analyzing samples and/or using analytical data for anti-doping research purposes; however, such a consent is not needed for quality assurance activities, when applied to Analytical Testing Procedures for prohibited substances or prohibited methods included in the prohibited list at the time of sample collection or other legitimate quality assurance process, as determined by WADA.

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

This is a new section which incorporates elements of ISL 2021 Sections 6.0 ("WADA External Quality Assessment Scheme") and 7.0 ("Evaluation of Laboratory EQAS and Routine Analytical Testing Performance"), while including the description of other WADA laboratory monitoring activities.

This new Section 6.0 is divided into two main Articles: Article 6.1 ("WADA Laboratory and ABP Laboratory Monitoring"), and Article 6.2 ("Evaluation of Laboratory Nonconformities").

Article 6.1: WADA Laboratory and ABP Laboratory Monitoring

Article 6.1 describes the three main WADA Laboratory Monitoring Activities, which include: (i) the "WADA EQAS Program"; (ii) "Laboratory and ABP Laboratory Assessments"; and (iii) "Removal of Samples for Analysis, Further Analysis or Quality Assessment Purposes".

Article 6.1.1: WADA EQAS

Article 6.1.1 provides a brief description of the WADA EQAS program. However, 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, will be included in the new Technical Document on EQAS (TD EQAS) under preparation, which is referenced in 2027 ISL Article 6.1.1.

Article 6.1.2: Laboratory and ABP Laboratory Assessments

This article provides a full overview of the WADA laboratory and ABP laboratory assessment activities, including a description of the types of assessments (Article 6.1.2.1) and assessment requirements (Article 6.1.2.2) including composition of assessment teams, assessment agendas, and assessment reports.

Article 6.1.3: Removal of Samples by WADA

Article 6.1.3 is the same as the current ISL 2021 Article 4.5.

Article 6.2: Evaluation of Laboratory Nonconformities

Article 6.2 provides a brief description of the WADA system of Laboratory and ABP Laboratory EQAS and routine Analytical Testing performance evaluation. However, full details on the WADA Laboratory performance evaluation procedures, including the classification of nonconformities, the process of review of Laboratory corrective action(s) to remedy nonconformities, the evaluation of False AAFs and False Negative Findings, and the WADA penalty point system, will be included in the new Technical Document on Performance Evaluation System (TD PERF) under preparation, which is also referenced in this Article 6.2.

Section 7.0 – Laboratory and ABP Laboratory Disciplinary Procedures

This section combines current ISL 2021 Article 4.6.4 (“Withdrawal of WADA Accreditation”), Article 4.6.5 (“Consequences of Suspended or Revoked Accreditation or Analytical Testing Restriction”), Article 4.6.6 (“Reinstatement of Suspended Accreditation or Lifting of the Analytical Testing Restriction”) and Article 4.6.7 (“Voluntary Cessation of Laboratory Operations”). Given the importance and impact of these sanctioning procedures, the ISL Drafting Team considers that they should be an integral part of the main body of this International Standard, and as such has been incorporated in the 2027 ISL as a new section.

Article 7.1.1 – ATR or Suspension of WADA Accreditation

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

This article describes the conditions that could lead to a suspension or ATR including: (i) the clarification at sub-article c), that the maximum number of allowed penalty points accumulated from EQAS and/or Analytical Testing will henceforth be described in the new TD PERF; (ii) the reference at sub-article d) to the reporting of a False AAF with consequences for an Athlete; (iii) the reference at sub-article l) to the failure to analyze the minimum number of Samples; and (iv) the reference at sub-article q) to a high number of major noncompliance(s) with the ISL, TDs and/or TLs which are identified during WADA Laboratory assessments and at a level that risks the full reliability and accuracy of Analytical Testing and the accurate reporting of test results.

Article 7.1.1.2: Suspension of Accreditation and ATR

This article clarifies that if the Lab EAG makes a recommendation to suspend or impose an ATR on a Laboratory based on major noncompliance(s) with the ISL, TDs and/or TLs based on the Laboratory's performance during the EQAS and/or during routine analytical testing, the Chair of the WADA Executive Committee may suspend or impose an ATR on the Laboratory.

Article 7.1.1.3: Immediate Provisional Suspension or Immediate Provisional ATR

Article 7.1.1.3 clarifies the ATR and Suspension steps to be taken specifically when a Laboratory reports a False AAF with consequences for an athlete. The Lab EAG will recommend a provisional Suspension or provisional ATR to the Chair of the WADA Executive Committee and in such case, the Laboratory shall cease all affected analytical activities. Furthermore, this article clarifies that even if the nonconformity is satisfactorily resolved, WADA may perform an assessment or send EQAS samples before the provisional Suspension or ATR is lifted. If the nonconformity is not satisfactorily resolved, the Lab EAG will recommend a full Suspension or ATR and the Laboratory shall have no right of appeal to a Disciplinary Committee (DC); however, the Laboratory may appeal to the Court of Arbitration for Sport (CAS).

Article 7.1.1.4: ATR and Suspension of Accreditation – No Disciplinary Proceedings

This article clarifies the ATR and Suspension steps to be taken when a Laboratory accumulates the maximum number of penalty points in the EQAS and/or routine Analytical Testing. The Lab EAG shall recommend a Laboratory Suspension or ATR to the Chair of the WADA Executive Committee. In this case, the Laboratory has no right of appeal to a DC; however, the laboratory has the right of appeal to CAS.

(Former) Article 4.6.4.4: Resolution Facilitation

The ISL Drafting Team has removed the concept of the 'Resolution Facilitation Session'. The opportunity for a Laboratory to hold a session with the Lab EAG in the case of Suspension or ATR has been introduced at 2027 ISL Article 7.1.1.5 or in the case of a Revocation at 2027 ISL Article 7.1.2.2.

Article 7.1.1.5: ATR and Suspension of Accreditation – Disciplinary Proceedings

This article clarifies that in the case that nonconformities (other than an accumulation of the maximum penalty points or reporting of a False AAF with consequences for the athlete) are identified, the Lab EAG may also recommend an ATR or Suspension. Before issuing a recommendation to the Chair of the WADA Executive Committee, the Laboratory shall receive notification regarding the Lab EAG recommendation for a Suspension or ATR and be provided with an opportunity to hold a session with the Lab EAG to discuss the associated nonconformities/terms or to accept the recommendation. As mentioned, the concept of the 'Resolution Facilitation Session' has been removed and the 2027 ISL refers to the opportunity for a session with the Lab EAG.

Article 7.1.1.5 sub-article b) clarifies the details and impact of the session on the Suspension or ATR decision outcome. Article 7.1.1.5 sub-article d) clarifies that the Laboratory has the right of appeal to CAS if a Suspension or ATR is imposed by the Chair of the WADA Executive Committee. Article 7.1.1.5 sub-article e) clarifies that a Laboratory ATR or Suspension should not imply the automatic withdrawal of its ISO/IEC 17025 accreditation which is to be independently assessed by the relevant Accreditation Body.

Article 7.1.2 – Revocation of WADA Accreditation

Article 7.1.2.1: Laboratory Noncompliances Leading to Revocation of WADA Accreditation

The conditions that justify a Revocation now include: (i) sub-article e), the repeated accumulation of the maximum allowed number of penalty points for the EQAS and/or Analytical Testing as determined by the application of the Points Scale Table to be described in the TD PERF; (ii) sub-article f), the repeated reporting of False AAFs or repeated failure to implement satisfactory corrective action(s) after the reporting of a False AAF; and (iii) sub-article r), the repeated failure to implement and document adequate R&D and Sharing of Knowledge activities.

Article 7.1.2.2: Revocation Procedures

Article 7.1.2.2 describes the procedure to be followed in the case of a Revocation including the holding of a session between the Laboratory and the Lab EAG prior to the Lab EAG's decision to issue a recommendation for Revocation. However, the session shall not be an option for a Laboratory which is already serving a Suspension or ATR. The Lab EAG shall rescind or issue the recommendation for Revocation following its evaluation of the Laboratory's explanations and/or additional evidence in this session. This article also stipulates the Laboratory's right to appeal the Lab EAG Revocation recommendation to a DC and to appeal the Revocation issued by the Chair of the WADA Executive Committee to CAS.

Article 7.1.6: Public Notice

This article clarifies that the public notice announcing a change in a Laboratory's accreditation status on WADA's website will include the terms and length of a Suspension or ATR and, in the case of an ATR, the relevant impacted test method or prohibited substance/prohibited method class shall be detailed.

Article 7.2: Consequences of Suspended or Revoked Accreditation or ATR

This article clarifies that the Laboratory shall continue to participate in the WADA EQAS during a Suspension or ATR and that WADA may require the Laboratory to analyze additional blind EQAS samples and/or perform a Laboratory assessment to evaluate the Laboratory's status.

Article 7.2.1: ATR

This article incudes further requirements including that the Laboratory shall immediately cease all analyses employing the affected analytical testing procedure(s) regardless of the reason(s) for the ATR (sub-article b)).

Article 7.2.2: Suspension of WADA Accreditation

This article includes further requirements including that the Laboratory shall immediately cease all Analytical Testing Procedure(s) (sub-article a)). The requirements have also been reorganized to improve readability and understanding. Article 7.2.2 sub-article i) has been introduced to clarify that in the case of a Blood ABP Analysis Suspension, the samples collected prior to the Suspension date may be analyzed by the Laboratory. The reporting in ADAMS shall include a comment regarding the Suspension so that the Testing Authority (or Results Management Authority) / Athlete Passport Management Unit can take this into account during the results management process. The reason for sub-article i) is that sending the ABP blood Samples to other Laboratory(-ies) for analysis within an acceptable timeframe is not feasible due to the negative impact of time on the integrity of the ABP blood samples.

Article 7.2.3: Revocation of WADA Accreditation

The ISL Drafting Team has placed the concepts relating to the transfer of samples in the case of Revocation into the body of this article instead of a comment.

Article 7.3: Extension of Suspension or Analytical Testing Restriction

Article 7.3 sub-article a) includes the scenario that in the case of an ATR, if a Laboratory has not satisfactorily corrected the noncompliance(s) that resulted in their ATR or if any additional ISL and/or TD and/or TL noncompliance(s) during the initial ATR are identified, Suspension proceedings may be initiated. Previously only an extension of the ATR or Revocation were possible outcomes for the initial ATR period. Article 7.3 sub-articles f) and g) have been introduced to clarify that the Suspension or Revocation of the Laboratory are possible outcomes if the Laboratory has not provided evidence determined to be satisfactory by WADA at the end of the extended ATR or Suspension period. In addition, sub-article h) states that a Laboratory subject to Suspension proceedings either at the end of an initial or extended ATR shall remain subject to the ATR or a Provisional Suspension (if applicable) until the completion of the Suspension proceedings.

Article 7.6: Suspension or Revocation of ABP Laboratory

A new article has been introduced to describe the procedure for the suspension or revocation of an ABP Laboratory.

Article 7.7: Reporting of False Analytical Findings During a Major Event

The ISL Drafting Team has removed the procedures in the case of a False AAF or False Negative Finding is reported during a Major Event from the 'Major Event' section and this information has been placed into Section 7.0 ("Laboratory and ABP Laboratory Disciplinary Procedures"). In the case of a False AAF, the Laboratory shall inform the Major Event Organization, determine the root cause of the nonconformity within twenty-four (24) hours of notification of the False AAF and report the implementation of satisfactory corrective actions to WADA within 48 hours, unless otherwise agreed to in writing. In case of a False Negative Finding, this article also stipulates that the Laboratory shall inform the Major Event Organization. This article further clarifies that the failure to implement satisfactory corrective action(s) in a timely manner will result in the imposition of a Laboratory Suspension or an ATR, as determined by WADA, and the cessation of Analytical Testing during the Major Event.

Section 8.0 – Code of Ethics for Laboratories and ABP Laboratories

Section 8 corresponds to current ISL 2021 Annex A. Given the importance and impact of these ethical requirements, the ISL Drafting Team considers that it should be an integral part of the main body of this International Standard, and as such has been incorporated as a new, standalone section of the ISL.

Article 8.5 – Duty to Preserve the Integrity of the World Anti-Doping Program and to Avoid any Detrimental Conduct

For the avoidance of any doubt, this article clarifies that any attempts of collusion between Laboratories, Probationary Laboratories and/or ABP Laboratories, as part of their participation in the WADA EQAS, shall constitute conduct that undermines or is detrimental to the World Anti-Doping Program or WADA and, therefore, shall be considered as a violation of the ISL Code of Ethics.

Part III – Annexes

- 2021 ISL Annex A (“ISL Code of Ethics”), is henceforth 2027 ISL Section 8.0.
- 2021 ISL Annex B (“Accreditation Requirements for Major Events”), is henceforth 2027 ISL Article 4.3 under 2027 ISL Section 4.0 (“Process and Requirements for WADA Laboratory Accreditation, ABP Laboratory Approval and Laboratory Accreditation for Major Events”).
- 2021 ISL Annex C (“Procedural Rules for the Disciplinary Committee of the ISL”), is henceforth 2027 ISL Annex A (with no content change).