2027 CODE & IS UPDATE PROCESS

International Standard for Laboratories

Concepts for Consideration and Feedback

Executive Summary

The International Standard for Laboratories (ISL) is a comprehensive, highly technical, and specialized International Standard that has undergone multiple rounds of revision since its first publication in August 2004. The ISL establishes the general norms and requirements for all WADA accredited anti-doping laboratory-related activities including:

- The definition of WADA laboratory normative documents (the ISL and its associated Technical Documents and Technical Letters, as well as Laboratory Guidelines and Technical Notes);
- The process of WADA accreditation or approval and the sanctions/disciplinary processes for laboratories which fail to comply with accreditation standards (Article 4.0);
- The structural/resources, process, and management requirements for the analysis of samples, including the performance of anti-doping tests and the secondary use of samples for research and quality assurance (Article 5.0);
- The WADA External Quality Assurance Scheme (EQAS) (Article 6.0); and
- The evaluation of Laboratory EQAS and routine performance (Article 7.0) as well as annexes describing the ISL Code of Ethics (Annex A), requirements for WADA accreditation for Major Events (Annex B), and the Procedural Rules for the ISL Disciplinary Committee (Annex C).

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, the ISL Drafting Team has identified the following concepts which it considers will help further strengthen and clarify the ISL as part of the 2027 Code & International Standard Update Process.

This document is a conceptual document where concepts and their related context will be explained, and stakeholder feedback as it relates to a concept shall be sought. This feedback will help to inform the ISL Drafting Team during the subsequent phase, the ‘First Drafting Phase’ following which stakeholders will have the opportunity to provide input directly as it relates to the proposed modifications or additions of the precise text and wording of the relevant articles in the ISL.

Concept #1 – Further Details of Requirements for WADA Laboratory Accreditation/Approval for the Athlete Biological Passport (ABP)

ISL Article 4.0 provides an explanation of the different steps and requirements for a laboratory to obtain WADA accreditation or WADA approval for the ABP. However, the ISL Drafting Team considers that additional details are needed to further clarify the requirements associated with the different stages of the accreditation/approval processes. Specifically, the ISL Drafting Team is seeking to propose the following updates:

- **Robust anti-doping programs in host country of applicant laboratory for WADA accreditation**. The ISL Drafting Team will consider proposing that a new laboratory applicant must demonstrate that its host country has a robust anti-doping program (i.e., minimum number of urine, blood, and ABP samples) before it shall be granted WADA accreditation as a laboratory or ABP laboratory in that country. This would ensure that a new laboratory is situated in a country with a strong national anti-doping program. It would also ensure that the new laboratory has a solid foundation and receives appropriate public/governmental support in that country. In addition, this may also help convince the host country National Anti-Doping Organization that the existing laboratory network is sufficient, and as a consequence, that the country should prioritize supporting the country's anti-doping program instead of looking for a new laboratory elsewhere.

- **Review of initial WADA accreditation fee**. The ISL Drafting Team will consider proposing a clearer definition of the costs needed or involved in the accreditation process prior to WADA accreditation or approval.

- **Candidate Laboratory**. The ISL Drafting Team will discuss establishing a clearer definition of the different stages in the three-year timeline for candidate laboratories: two years to prepare for the pre-probationary test (PPT) EQAS and assessment; and one year to address issues related to the PPT EQAS.

- **Probationary Laboratory**. The ISL Drafting Team will consider proposing the establishment of a time limit for probationary laboratories, which should allow increased flexibility in the timelines for implementation of improvements and corrections based on a Final Accreditation Test (FAT) and on-site assessment of probationary laboratories.

- **Requirement for Laboratories to implement a Research & Development (R&D) Program**. The ISL Drafting Team will consider defining a clearer framework as it relates to the requirements for laboratories' R&D programs. For example, the current requirement that 7% of a laboratory's annual budget be directed towards R&D may not necessarily be the best measure of a strong scientific research program, which can benefit the anti-doping system. In general, the ISL Drafting Team considers that the existing requirements are minimalistic and could be improved by integrating more descriptive indicators and qualifying the expectations from the research (e.g., level of novelty and innovation). Moreover, the annual periodicity of the evaluations of R&D programs is ill-adapted to the dynamics of scientific research and could be extended (for example, to two or three years), which the ISL Drafting Team considers would be more appropriate for the evaluation of this type of activity.

- **Minimum number of annual samples**. The ISL Drafting Team will consider proposing revisions to the current benchmark of 3,000 samples in order to incorporate the complexity and relevance to perform analyses in different matrices (e.g., blood and dried blood spot (DBS)).

- **ABP approval**. The ISL Drafting Team will consider whether a laboratory that is approved by the WADA Executive Committee (ExCo) as a candidate laboratory for WADA accreditation should be automatically qualified as a candidate laboratory for WADA ABP approval, as this would allow the candidate laboratory to begin the process of becoming an ABP laboratory pursuant to ISL Article 4.7.2 (i.e., without requiring the candidate laboratory to revert to the ExCo in order to be specifically granted its ABP laboratory status). If adopted, the WADA technical evaluation could then proceed as described in ISL Article 4.7.2.

- **Analytical Testing Restrictions (ATR)**. ISL Article 4.6.6.1 establishes that an ATR can be extended to a maximum of twelve months, following which the laboratory would be revoked if the laboratory has not provided satisfactory evidence that it has corrected the issues that led to the ATR. Since an ATR is limited to specific Analytical Testing Procedure(s) or the analysis of a particular class(es) of prohibited substances or prohibited methods, the ISL Drafting Team will consider whether a suspension should be imposed on the laboratory before revoking the laboratory's accreditation.

Concept #2 – WADA-specific Analytical Testing Procedures

The ISL establishes the requirements for laboratories to implement test methods that are classified as WADA-specific analytical testing procedures. Nevertheless, it has become evident that revisions are required to expedite the application of certain routine analytical procedures, which may also lead to a more effective use of internal human resources for the WADA Laboratory Team, which should otherwise be reviewing all laboratory applications for the implementation of these procedures, including validation reports and standard operating procedures (SOP). This could be considered a task of the ISO/IEC 17025 accreditation bodies.

Accordingly, the ISL Drafting Team will consider proposing revisions to the definition and approval process to include WADA-specific analytical testing procedures into a laboratory's scope of accreditation before application to the analysis of doping control samples.

Concept #3 – Monitoring of Accreditation Status : Disciplinary Proceedings

ISL Articles 4.6.4.1.2 and 4.6.4.4 describe when a resolution facilitation session (session) may be offered to a laboratory, which has been recommended by the Laboratory Expert Advisory Group (Lab EAG) for an analytical testing restriction, suspension, or revocation of its accreditation. In practice, if a session is requested by a laboratory, it may prolong the disciplinary proceedings instead of shortening them as originally intended.

Therefore, in order to provide the laboratory with an efficient process so that it can focus on the resolution of identified non-conformities instead of facing a lengthy disciplinary process, the ISL Drafting Team will consider proposing revised language to clarify that a laboratory may, upon notice of the Lab EAG's recommendation, either accept the Lab EAG's recommendation, or request disciplinary proceedings be initiated as soon as reasonably possible in order to provide any evidence that the Lab EAG's recommendation should not be accepted.

Concept #4 – Secondary Use of Samples : Research and Quality Assurance

ISL Article 5.3.12 establishes the conditions for secondary use (research and quality assurance) of doping control samples. However, the concepts of research and quality assurance must be better defined, since the

requirements for the use of doping control samples differ for these activities (namely, on the need for an athlete's consent, and consequent protection of athletes' privacy and personal information). Assuredly, many national and institutional ethics policies consider data collected for quality assurance (QA) and quality improvement (QI) activities to be outside the scope of research ethics review and consent procedures. In this respect, both the Code and ISL Article 5.3.12.2 already include language that allows for a broad interpretation of QA/QI activities as well as for the potential overlap with activities that would typically be considered as research related (for example, see the comment to Code Article 6.3, which mentions that the use of samples and related information for quality assurance, quality improvement, method improvement and development or to establish reference populations, is not considered research). Furthermore, with the increased sophistication of doping practices (e.g., new substances, new masking strategies, new doping methods), it is essential that anti-doping laboratories have access to a sufficient number of samples in order to keep pace with new analytical challenges. Therefore, samples collected in the context of doping control represent a valuable resource for anti-doping research and QA/QI.

Accordingly, the ISL Drafting Team will consider proposing a thorough review and update of the ISL in order to assist laboratories and anti-doping organizations in implementing a uniform approach to the use of samples for research, QA, or QI purposes once they are no longer needed for the purposes of doping control, including long-term storage for further analysis, as otherwise such samples would be destroyed. An update to the ISL in this respect should describe the conditions that would allow the secondary use of samples without athlete consent. This proposal would be based on the presumption that such activities do not go beyond the initial objectives of the sample collection, namely, to test the sample for the presence of such prohibited substances and prohibited methods. This noted, and whether consent is required or not, any samples that are used for secondary purposes shall always be adequately anonymized to avoid athlete identification.
Moreover, the ISL Drafting Team proposes that the concept of research be defined in the Code and other related documents in a clearer, more assertive, and justified manner so as to position research as one of the main drivers of performance for the global anti-doping system and, by consequence, as a contribution to the principle of equity between athletes.

Concept #5 – Clarification of Further Analysis

In accordance with the relevant Code requirements, the ISL establishes the conditions under which samples may be subjected to further analysis. Nonetheless, there is insufficient clarity regarding the performance of certain confirmation procedures that may occur after an adverse analytical finding has been reported (e.g., confirmations by GC/C/IRMS based on ADAMS notifications of an atypical passport finding or upon request by the athlete passport management unit or the testing authority) and which may then require an athlete or hearing panel's consent or approval in order to be carried out.

The ISL Drafting Team shall consider proposing that certain confirmation procedures (e.g., GC/C/IRMS tests for atypical passport findings related to the steroid profile), which are triggered by initially suspicious results from analyses already performed on samples (e.g., initial testing procedures for the steroid profile), are not considered as further analysis, but as part of the ongoing analytical testing process, even if results for other analyses have already been reported for the sample. This would ensure that if an adverse analytical finding has been reported and the athlete has been charged with an anti-doping rule violation, those confirmation procedures could be performed without requiring the athlete or hearing panel's consent or approval.

Concept #6 – Assuring the Validity of Analytical Results

ISL Article 5.0 describes the general requirements (e.g., structural, resource-related, process and management requirements) for the analysis of samples. Amongst them, the implementation of appropriate quality control procedures is essential to ensure the validity of analytical results.

The ISL Drafting Team will consider an improved description of the quality control procedures to be implemented by laboratories, including the use of reference materials (metrological traceability including stock and working solutions, verification of identity and purity checks, etc.), quality control (QC) samples and QC-charts, internal standards, internal quality assessment schemes (iQAS) and internal audit programs.

Concept #7 – Update of WADA EQAS

ISL Article 6.0 describes the WADA External Quality Assessment Scheme (EQAS), which requires updating following the implementation of an EQAS Management System in compliance with the ISO 17043: 2023 international standard applicable to proficiency testing providers.

The ISL Drafting Team will consider proposing revisions to the distribution of WADA EQAS modalities (i.e., number of rounds/samples/type of EQAS) to make it more efficient and cost-effective with an increased focus on education and improvement of laboratory harmonization and analytical capacity, while also maintaining the program as an important tool for laboratory performance monitoring. The ISL Drafting Team will also consider proposals to integrate the introduction of a DBS EQAS program into the ISL. Furthermore, the ISL Drafting Team will consider reviewing the allocation of penalty points in the WADA EQAS based on the revised EQAS sample distribution and application of a new Bayesian statistical approach for evaluation of Laboratory EQAS performance. Depending on the extent of the proposed changes, this may lead to a reduction of the EQAS budget as well as a better assignment and more effective use of WADA human resources for EQAS. It may also require revisions to the existing contract with the EQAS Sample Provider and the identification of a new provider for DBS EQAS samples.

Concept #8 – Laboratory Right of Appeal : Evaluation of Non-Conformities identified during Routine Analysis

While the ISL and the WADA EQAS Management System respectively provide guidance on the appeal process for laboratory sanctions affecting their accreditation status (e.g., suspensions, analytical testing restrictions, revocations) and EQAS performance decisions, there is no explicit mention of a laboratory's right of appeal against sanction-related decisions (e.g., assignments of penalty points) for non-conformities identified during routine sample analysis.

To further strengthen the process of laboratory performance evaluation, while maintaining fairness and impartiality, the ISL Drafting Team will consider adding an Article to the ISL that addresses a laboratory's right of appeal against decisions that may lead to the assignment of penalty points (e.g., evaluation of non-conformities identified during routine sample analysis) and which could eventually affect the WADA accreditation or approval status of that laboratory.