

## **INTERNATIONAL STANDARD FOR LABORATORIES (ISL) (FOLLOWING THE FIRST CONSULTATION PHASE)**

### **SUMMARY OF MAJOR PROPOSED CHANGES FOUND IN THE FIRST DRAFT OF THE INTERNATIONAL STANDARD FOR LABORATORIES (ISL)**

This review of the ISL was triggered by some important changes that could not reasonably wait until the new 2021 Code.

The modifications in the 2019 ISL v1. 10.0, as compared to the current 2016 ISL v. 9.0, are substantial and include, for example:

1. Important modifications and updates have been introduced to Section 1 (Introduction) regarding the description of the different WADA Laboratory standards, including a new mandatory standard that becomes an integral part of the ISL (Technical Letters);
2. The section of ISL definitions has been revised to include new metrological and method validation terms;
3. Important modifications and updates have been introduced to Section 4 (Process and Requirements for WADA Laboratory Accreditation) in regards, for example, to Laboratory independence, a better description of the three (3) phases of the Laboratory accreditation process (candidate, probationary and accredited Laboratory), the consequences of a Laboratory suspension or revocation (with emphasis, for example, on the steps to be taken with the samples under custody of a suspended or revoked Laboratory) and the criteria for approval of a Laboratory for ABP (blood) analyses;
4. A new Section 5 (Analysis of Samples) has been created, where the previous Sections 5 (analysis in urine) and 6 (analysis in blood) have been merged. The structure of this Section 5 follows the newly approved ISO/IEC 17025: 2017 international standard (applicable to calibration and testing laboratories), and includes important updates on sample storage and further analysis, method validation requirements , etc.;
5. The previous Annex A – EQAS has been split into two new Sections: Section 6 (EQAS Program) and Section 7 (Laboratory Performance Evaluation), and requirements have been thoroughly revised.

In the new Section 7, the WADA system for evaluation of Laboratory EQAS and routine Analytical Testing performance has been enhanced with the objective of setting a transparent and balanced procedure for evaluation of Laboratory and probationary laboratory operations, based on the principle of proportionality and focused on improving Laboratory's Analytical Testing capabilities and, in the case probationary laboratories, their readiness for obtaining WADA accreditation. This system of Laboratory evaluation is ultimately aimed at maintaining the confidence in and strengthening of the WADA anti-doping Laboratory system.

6. A new Annex B: Procedural Rules for the Disciplinary Committee of the ISL, has been added, whereas the revised ISL Code of Ethics remains as Annex A.