



**WORLD CONFERENCE
ON DOPING IN SPORT**
KATOWICE 2019 | 5-7 NOVEMBER

SESSION 15

The International Standard for Laboratories (ISL)

Richard Young, Lead Drafter, ISL





ISL Version 10.0 (2019)

ISL Version 10.0

- Approved by WADA ExCo on 15 May 2019
- Came into force on 1 November 2019
- Significant changes made, including:
 - Aligning relevant provisions of the ISL with new ISO/IEC 17025:2017
 - Adding Technical Letters (TLs) and Technical Notes (TNs) to the ISL
 - Updating the sections on Laboratory Accreditation, Sample Analysis, WADA External Quality Assessment Scheme (EQAS) and Laboratory Performance Evaluation
 - New Annex B: Procedural Rules



ISL Revision: Version 10.0

Working Group

- **Dr Tiia Kuuranne** (Director, Lausanne Laboratory; member of LabEG)
- **Dr John Miller** (former Chairman, LabEG)
- **Dr Terence Wan** (Chairman, LabEG)
- **Richard Young** (Lawyer; external counsel; main drafter)
- **Mr Adam Klevinas** (External counsel)
- **Dr Catrin Goebel** (President, WAADS; Director, Sydney Laboratory; member, LabEG) - *observer*

*Supported by WADA Science and Legal
Departments*



Objectives of the Revision

- Important changes that could not reasonably wait until the new 2021 Code
 - Revised ISO/IEC 17025: 2017 Standard (Nov. 2017)



ISL Version 10.0 – Revision



- **Section 1:** Laboratory standards (Technical Documents, Technical Letters; Laboratory Guidelines, Technical Notes)

- **Section 4**
 - Laboratory independence
 - Flexible scope of ISO/IEC 17025 accreditation
 - Fate of samples after laboratory accreditation suspension/revocation
 - Laboratory disciplinary process
 - Process and criteria for approval of approved/Athlete Biological Passport (ABP) laboratories

ISL Version 10.0 – Revision (Cont'd)



- **Section 5 (+ Section 6): Sample Analysis in Urine and Blood**
 - Removal of duplications and inconsistencies
 - Update in line with new Technical Documents
 - Update of some compliance decision criteria (e.g., B-sample confirmations for non-threshold substances)
 - Further analysis and split samples
 - Method validation requirements

- **Section 6: EQAS**
 - More emphasis on double-blind program and more flexibility in distribution of EQAS samples according to lab performance

ISL Version 10.0 – Revision (Cont'd)



- **Section 7**
 - Overhaul of the Laboratory Performance Evaluation System (more balanced and based on a risk analysis approach)

- **Annex A: Code of Ethics**
 - Ensure protection of the anti-doping system in consideration of the issues faced over the last few years (e.g., Russia)

- **Annex B: Procedural Rules of the Disciplinary Committee (new)**



ISL Version 11.0 (2021)

ISL Revision: Version 11.0

Working Group

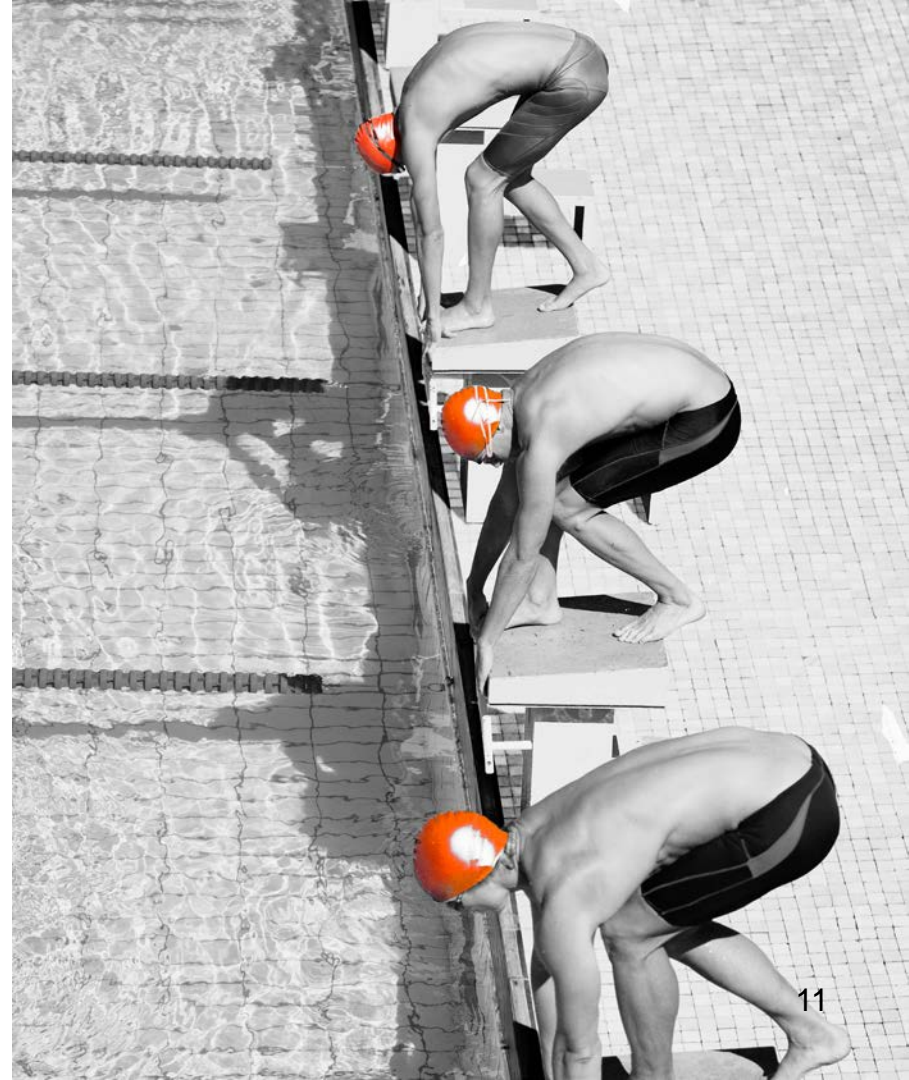
- Dr Tiia Kuuranne
- Dr Bruno Garrido (member LabEG)
- Dr Terence Wan
- Mr Richard Young
- Mr Adam Klevinas
- Dr Catrin Goebel - *observer*

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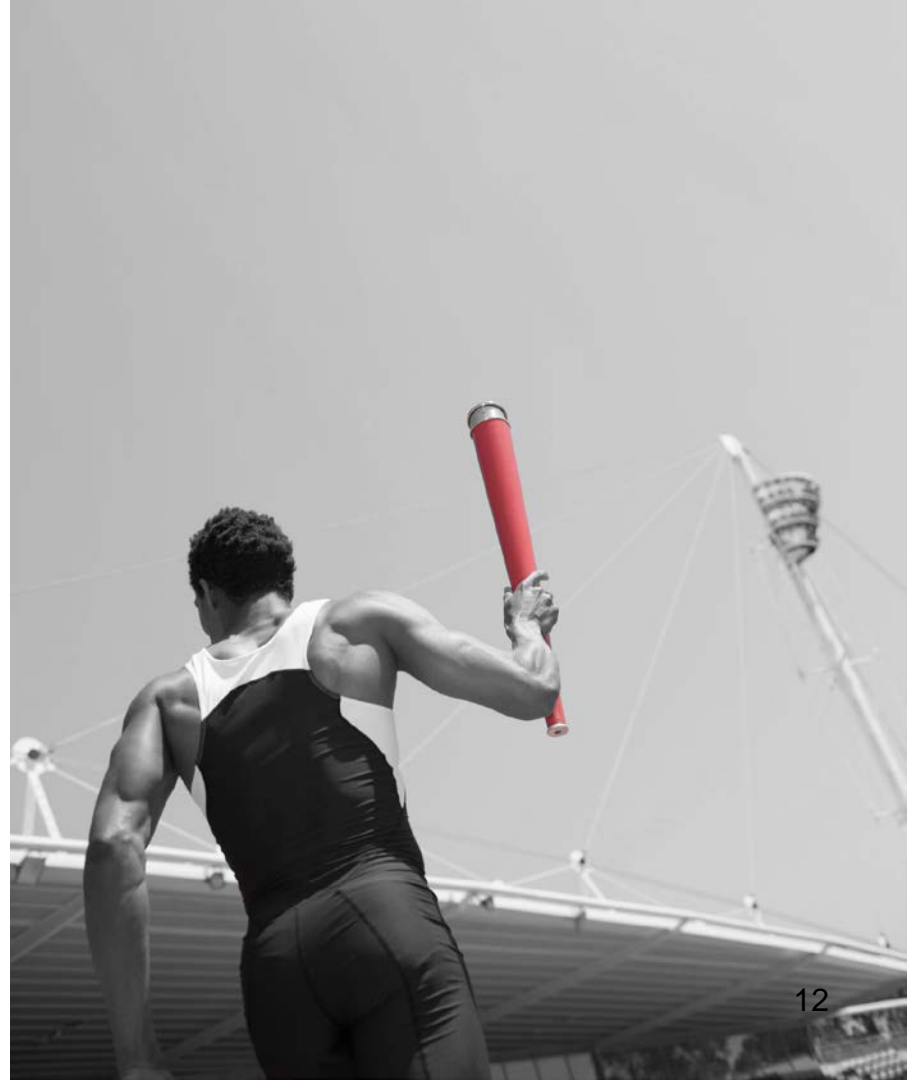
Objectives of the Revision

- Alignment with 2021 Code
- Gap analysis vs. ISO 17025 (2017)
- Laboratory independence
- Reformat to enhance clarity (e.g., New Annex B: Accreditation requirements for Major Events)
- Effective implementation of Technical Documents with focus on further analysis



Objectives of the Revision (Cont'd)

- Criteria for assessment of laboratory research activities
- Use of samples for research
- Analysis of samples from non-Signatories
- Analysis of samples with irregularities
- Timing of B-sample confirmations



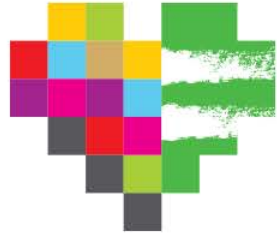
Schedule of ISL Version 11.0 Revision



- **Circulation to stakeholders**
 - Dec. 2019 – March 2020

- **Review by Working Group, presentation to LabEG and laboratory directors**
 - March 2020

- **Approval by WADA ExCo**
 - May 2020
 - Effective date: 1 January 2021



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