

THIRD ILAC-WADA COMMUNIQUE JOINT DOCUMENT COOPERATION BETWEEN ILAC AND WADA

FOR THE ATTENTION OF ALL ACCREDITATION BODIES INVOLVED IN
THE ISO/IEC 17025 ACCREDITATION OF WADA ANTI-DOPING LABORATORIES

INTRODUCTION

This is the Third ILAC-WADA Communiqué issued with respect to the ILAC-WADA cooperation regarding the WADA anti-doping laboratories. The First Communiqué was released in August 2004 during the early stages of the cooperation, and the Second in November 2009. WADA and ILAC also signed a Memorandum of Understanding (MoU) in November 2007, which has been revised and confirmed in 2010, 2013 and 2016:

- November 2007 - Initial MoU signed at the Third World Conference on Doping in Sport, Madrid, Spain;
- October 2010 - The MoU confirmed during the ILAC General Assembly organized in Shanghai, China;
- November 2013 - The MoU re-signed at the Fourth World Conference on Doping in Sport in Johannesburg, South Africa;
- November 2016 - The MoU reconfirmed at the ILAC General Assembly in New Delhi, India.

The MoU outlines the nature and context of the cooperation and should be consulted in association with this document. The current MoU can be found on ILAC's website: <https://ilac.org/about-ilac/partnerships/international-partners/wada/>.

WADA anti-doping laboratories are required to maintain dual accreditation by demonstrating compliance with two international standards, namely:

- i) ISO/IEC 17025 *General requirements for the competence of testing and calibration laboratories*; and
- ii) WADA's International Standard for Laboratories (ISL).

Cooperation between ILAC and WADA, for the two complementary accreditation activities, provides an opportunity to achieve greater consistency in laboratory assessment and compliance with the two international standards.

The ISL requires that the ISO/IEC 17025 accreditation of WADA anti-doping laboratories be granted by accreditation bodies (ABs) that are signatories to the ILAC Mutual Recognition

Arrangement (MRA), and this accreditation serves as the prerequisite for WADA's laboratory accreditation. Thus, it is required that ABs take also into account the ISL, its related Technical Documents (TDs) and Technical Letters (TLs), in addition to ISO/IEC 17025, when performing an assessment of the WADA anti-doping laboratories.

While it is expected that effective collaboration in this area will contribute to increased consistency in the application of the existing standards by WADA anti-doping laboratories worldwide, ILAC and WADA also recognize that the ABs have their own individual procedures to grant accreditation and monitor compliance with ISO/IEC 17025 and the ISL.

This Third ILAC-WADA Communiqué provides comprehensive information on the roles and responsibilities, as agreed between ILAC and WADA, in regard to the sharing of information between WADA and any ILAC MRA Signatory AB that accredits an anti-doping laboratory.

1. PRACTICAL MECHANISMS FOR COOPERATION

The ILAC-WADA cooperation is supported by a committee system which provides practical guidance on how the cooperation can function in the most appropriate and effective manner (provides guidance to both the ABs and the accredited anti-doping laboratories).

According to the ILAC-WADA MoU, there should be at least annual meetings between the two organisations, and this is achieved through the ILAC-WADA Liaison Group. Membership in the ILAC-WADA Liaison Group is restricted to the ILAC member accreditation bodies which are actively engaged in accrediting anti-doping laboratories that are WADA-accredited or in the probationary phase of WADA accreditation, WADA staff and WADA representatives. Non-confidential discussions or recommendations from this Group are reported back to the ILAC AIC through the Convener(s) while confidential information is shared with the Group members only. Further details on the membership of the Group and the Terms of Reference are available in the members area of the ILAC website on the Accreditation Committee page.

While the specific responsibilities of the ABs and WADA within the cooperation are detailed below, it is expected that appropriate communication is maintained between the ABs and WADA whenever there is a need for discussion or clarification regarding matters of anti-doping laboratory accreditation.

2. ACCREDITATION BODY RESPONSIBILITIES

2.1 AB responsibilities in relation to the anti-doping laboratory:

- a) Provide information to WADA and ILAC on the impact, if any, of the ILAC-WADA cooperation in relation to the AB's assessment and reporting processes;

- b) Whenever considered appropriate, inform WADA of the intention to carry out an assessment and seek advice from WADA, if necessary, on any specific matters that may require AB attention;
- c) When circumstances allow, invite, as observer(s), WADA representative(s) to AB's assessment(s);
- d) Incorporate the monitoring of compliance with the WADA ISL, TDs and TLs into the routine assessments of WADA anti-doping laboratories (the recommended sections of the ISL to be assessed are detailed in Annex 1 to this Communique). WADA Laboratory Guidelines (LGs), although not mandatory, should also be considered as they offer recommendations of best practice;
- e) In accordance with the AB's procedures (including the use of a flexible scope of accreditation if allowed - refer to the ILAC-G29/06:2020 and the List of WADA-specific Analytical Testing Procedures) and the ISL, review new methodologies and/or analytes that have been introduced by the laboratory;
- f) Require the laboratory to make available for review (prior to or at the time of assessment) any confidential WADA reports and individual WADA letters resulting from the laboratory's participation in the WADA blind and double-blind External Quality Assessment Scheme (EQAS) (further details are provided later in this document);
- g) Respond to requests by WADA to follow-up on nonconformities identified either during WADA laboratory assessments or by other means. Such requests would only relate to areas that are within the AB's range of responsibilities according to the ILAC-WADA cooperation;
- h) Advise the laboratory that WADA will be consulted, where necessary, for the resolution (or close-out) of any nonconformities;
- i) Make an Assessment Summary available to WADA. Based on an agreement between the laboratory and the AB, the AB should provide the Assessment Summary; however, the laboratory may also take responsibility to forward the Assessment Summary to WADA (mechanisms for communication between the AB and WADA are described later in this document);
- j) Formally inform WADA in writing:
 - 1. immediately when significant nonconformities are identified during an assessment, or from information obtained outside of an assessment (e.g. from a complaint), that may affect the ISO/IEC 17025 accreditation status of the laboratory. The AB is to inform the laboratory that it will be contacting WADA and the reason(s);
 - 2. when a laboratory's ISO/IEC 17025 accreditation is at risk of being suspended or withdrawn, or its accreditation status or scope of accreditation changes in a way that could impact its role as an anti-doping laboratory;
 - 3. when the suspension of an anti-doping laboratory has been lifted and the effective date of its return to ISO/IEC 17025 accredited status.

2.2 AB responsibilities in relation to ISL-trained assessors:

- a) Include a WADA ISL-trained assessor in the assessment team for initial assessments, surveillance visits and reassessments and ensure that the ISL assessor is selected from the WADA List of ISL-Trained Assessors on WADA's website (see WADA responsibilities);
- b) Ensure ISL assessors maintain their competence;
- c) Inform WADA when a WADA ISL-trained assessor is no longer employed by or under contract with the AB and propose alternative candidate(s) to undergo ISL training at the next training opportunity.

3. WADA RESPONSIBILITIES:

- a) Provide regular training opportunities and updates, as required, for nominated WADA ISL assessors;
- b) Maintain a current list of WADA-trained ISL assessors on WADA's website;
- c) Define the sections of the ISL that should be prioritized by the AB during laboratory assessments and advise of specific areas of interest relating to the laboratory;
- d) Keep ABs informed of updates to the ISL and updates to existing or new TDs, TLs or other applicable normative documents;
- e) Provide information on WADA-specific Analytical Testing Procedures to ISL-trained assessors and ABs;
- f) Whenever considered appropriate, inform AB of the intention to carry out an assessment and seek AB advice, if necessary, on any specific matter(s) that may require WADA attention;
- g) When circumstances allow, invite, as observer(s), AB representative(s) and/or their ISL-trained assessor(s) to WADA's assessments;
- h) Formally inform the AB in writing of:
 1. any analytical testing restriction (ATR), suspension or revocation of a WADA-accredited laboratory or ABP laboratory;
[ABP laboratory: A laboratory not otherwise accredited by WADA, which is approved by WADA to apply Analytical Methods and processes in support of the hematological module of the *Athlete Biological Passport (ABP)* program and in accordance with the criteria for approval of non-accredited laboratories for the *ABP*. ISL 2021, Art 3.2];
 2. any issues relating to the anti-doping laboratory that may require particular consideration by the AB (e.g. issues related to the method(s) on the scope of accreditation);
 3. any issues related to a laboratory's preparation and testing services for a Major Event (e.g. Olympic Games).
- i) WADA may also ask the AB to follow-up on any matters identified (either during a WADA laboratory assessment or by other means) that fall within the AB's area of coverage according to the ILAC-WADA cooperation.

4. COVERAGE OF THE WADA ISL, TDs AND TLs DURING ASSESSMENT

The WADA ISL and its related TDs and TLs are published on WADA's website at <https://www.wada-ama.org/en/what-we-do/science-medical/laboratories>.

The AB and WADA have particular responsibilities in relation to the assessment of the anti-doping laboratories against the WADA ISL, its relevant TDs and TLs and these are listed in Annex 1 to this Communiqué.

5. ASSESSMENT REPORTS

5.1 The Assessment Summary

The aim of the Assessment Summary is to provide WADA with relevant information on the outcome of the AB assessment of the anti-doping laboratory including any corrective action requirements to address identified nonconformities. As per 2.1 i., the Assessment Summary should be provided to WADA, in English or French, by the AB; however, should the laboratory prefer to send the information directly to WADA, the Assessment Summary shall be provided within a reasonable timeline.

5.2 The Assessment Summary should cover, as a minimum, the following:

- a) The type of visit (assessment, reassessment, surveillance, scope extension) and the scope of that visit;
- b) The names and roles of the assessors, indicating who is the WADA-trained ISL assessor;
- c) A list of findings, recommendations and/or nonconformities identified during the assessment;
- d) A specific statement that all nonconformities identified have been addressed by the laboratory and closed-out by the AB, and if not, the expected timeframe/deadline for action(s);
- e) The AB's recommendation on granting (or otherwise) the ISO/IEC 17025 accreditation and/or any changes to the ISO/IEC 17025 scope of accreditation of the anti-doping laboratory;
- f) A specific statement that EQAS performance was evaluated and, if applicable, that the laboratory satisfactorily implemented EQAS-related corrective actions into laboratory's routine practice;
- g) Issues, if any, related to laboratory impartiality and laboratory resources including staff (particularly in the event of senior staff departures), facilities and equipment that may adversely impact the quality of the laboratory's activities;
- h) Information on the next intended assessment (expected date and purpose).

5.3 Provision of the full Assessment Report

If the AB produces a full Assessment Report, then it should be provided to WADA only upon request. Should such a request be made, WADA will also inform the laboratory of this request at that time.

5.4. Provision of further information

The AB is required to provide further assessment information upon request by WADA.

5.5. WADA External Quality Assessment Scheme (EQAS) Information

WADA anti-doping laboratories (accredited and probationary laboratories, as well as ABP laboratories) shall make available all information regarding their WADA EQAS performance, at each assessment or surveillance visit or as requested by the AB. The AB should contact WADA if there is any difficulty in obtaining this information.

This is particularly important when assessing the introduction of a new method or procedure into the laboratory's ISO/IEC 17025 scope of accreditation. For some particular procedures, WADA will require the successful participation of the laboratory in an EQAS (e.g. a WADA educational EQAS) or inter-laboratory collaborative study before ISO/IEC 17025 accreditation is granted for the method. This will be specified in a TD or Laboratory Guidelines.

In addition, some specific procedures, as determined by WADA, should not be considered within a flexible scope of accreditation (refer to the List of WADA-specific Analytical Testing Procedures).

ANNEX 1

Areas of the WADA ISL 2021 to be covered by the AB:

- All of Section 5.0 Application of ISO/IEC 17025 to the Analysis of Samples *;
- Relevant clauses of ISL Section 6.0 WADA EQAS and Section 7.0 Evaluation of Laboratory EQAS and Routine Analytical Testing Performance (Art. 6.3 and Section 7.0 are important if the AB is to evaluate the Laboratory's EQAS performance and how the laboratory has addressed any EQAS nonconformities);
- Annex A - Code of Ethics for Laboratories and ABP Laboratories;
- Annex B - Accreditation Requirements for Major Events (only if Laboratory is preparing for a Major Event, e.g. Olympic Games).

In addition, laboratory's compliance with WADA's TDs and TLs shall also be evaluated during the AB assessments. The evaluation of conformity with LGs should also be considered, when applicable. The most updated version of these documents can be found on the WADA website:

- Technical Documents

https://www.wada-ama.org/en/resources/search?f%5B0%5D=field_resource_collections%3A30

- Technical Letters

https://www.wada-ama.org/en/resources/search?f%5B0%5D=field_resource_collections%3A227

- Laboratory Guidelines

[https://www.wada-ama.org/en/resources/search?f\[0\]=field_resource_collections%3A198](https://www.wada-ama.org/en/resources/search?f[0]=field_resource_collections%3A198)

* During the WADA ISL assessors training sessions, WADA provides detailed feedback on those areas of laboratory operations that warrant particular attention during their assessments.