

SECOND ILAC COMMUNICATION

JOINT DOCUMENT COOPERATION BETWEEN WADA AND ILAC

FOR THE ATTENTION OF ALL ACCREDITATION BODIES INVOLVED IN THE ACCREDITATION OF LABORATORIES ALSO ACCREDITED BY THE WORLD ANTI-DOPING AGENCY (WADA)

Introduction

This is the Second Communication to be issued with respect to the WADA/ILAC cooperation regarding anti-doping laboratories. The First Communication was released in August 2004 during the early stages of the cooperation. WADA and ILAC have since signed a Memorandum of Understanding (MoU) dated 15 November 2007, and this can be obtained from the ILAC web site. The MoU provides useful background information on the nature and context of the cooperation and should be consulted in association with this document.

The cooperation has provided the opportunity for the ISO/IEC 17025 assessment undertaken by the ILAC member body to be considered as the basis for accreditation by WADA, in addition to the WADA International Standard for Laboratories (ISL). ILAC and WADA have at all times been aware of the need to consider, as far as is appropriate and possible, existing individual accreditation body procedures. It is also expected that effective collaboration in this area will contribute to the provision of a better service, and greater consistency in standards, for WADA accredited anti-doping laboratories.

This Second Communication provides comprehensive information on the responsibilities that have now been agreed between ILAC and WADA in regard to the sharing of information between WADA and any ILAC accreditation bodies that accredit anti-doping laboratories. These are detailed at the end of this document.

Information on the process for cooperation between ILAC and WADA is also included in this document, as is information on possible future directions for the cooperation.

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 in regard to both organisations.

According to the WADA ILAC MoU, there should be at least annual meetings between the two organisations. This is achieved through a once or twice yearly meeting of the ILAC/WADA Liaison Group. Members of the Liaison Group include accreditation body members of the ILAC Accreditation Committee (AIC) who are involved in the accreditation of anti-doping laboratories, WADA representatives and WADA ISL assessors. Any discussions or recommendations in this group are reported back to the ILAC AIC through the Convener. (Further details on the membership of the group and the records of these discussions are available in the Liaisons section of the ILAC web site.)

There is also a dedicated ILAC liaison member who attends relevant meetings of the WADA Laboratory Committee.

While specific responsibilities for ABs and WADA in regard to the cooperation are detailed below, it is expected that appropriate communication will occur between ABs and WADA where there is a need for discussion or clarification around matters of laboratory accreditation.

Accreditation Body and WADA Responsibilities and Roles

Accreditation body responsibilities

- **In relation to the anti-doping laboratory the accreditation body will:**
 - provide information on the practical effects of the ILAC/WADA cooperation regarding assessment and reporting processes;
 - incorporate the WADA ISL and the Technical Documents into the routine assessment that will be conducted against ISO/IEC 17025;
 - require that any reports and individual letters relating to their participation in WADA External Quality Assessment Scheme (EQAS) activities are made available for review at the time of any assessment visit (Further details are provided later in this document);
 - advise the anti-doping laboratory that the resolution (or close-out) of any non-conformities will be determined by the accreditation body and that WADA will be consulted where necessary;
 - make available an Assessment Summary to the laboratory and to WADA (Mechanisms for communication between the AB and WADA are described later in this document);
 - follow their usual reporting practice in regard to the full assessment report (Further details are provided later in this document);
 - inform WADA immediately when:
 - an anti-doping laboratory's accreditation is suspended or withdrawn or its accreditation status or scope changes in a way that could affect its role as an anti-doping laboratory;
 - the suspension of an anti-doping laboratory has been lifted and the effective date of its return to accredited status;
 - the non-conformities identified may affect the accreditation status of the anti-doping laboratory.

- **In relation to the ISL-trained assessor, the accreditation body will:**
 - include an ISL trained assessor in the assessment team;

- ensure that ISL assessors are chosen from the WADA List of ISL Trained Assessors (see WADA responsibilities);
- encourage ISL assessors to maintain their expertise and to participate in opportunities to share their knowledge and expertise in the assessment of anti-doping laboratories;
- make all attempts to maintain ISL assessors in their position to allow sufficient time to gain and share expertise and experience.

WADA responsibilities

WADA will undertake the following, as and when required:

- Define the parts of the WADA ISL that are to be covered by accreditation bodies at the time of assessment, and any specific areas of interest or concern if relevant;
- Provide regular training opportunities, as required, for nominated WADA ISL assessors and information updates to these ISL assessors;
- Maintain a current list of the WADA trained ISL assessors on the WADA website;
- Provide technical / scientific advice to the ISL assessors and accreditation bodies as and when required;
- Where possible, provide information on new WADA-approved methods to ISL assessors and accreditation bodies;
- WADA will inform the accreditation body immediately of:
 - any suspensions or revocations of anti-doping laboratories when these occur;
 - any issues relating to the anti-doping laboratory that may require particular consideration;
 - any anti-doping laboratory implications relating to forthcoming Major Events (e.g. Olympic Games).

Coverage of the WADA ISL during Assessment

The *WADA International Standard for Laboratories* (ISL) came into force in January 2004. Since then, as part of WADA's ongoing efforts to enhance worldwide anti-doping activities under the World Anti-Doping Code (Code), the ISL has undergone several revisions based on consultations with WADA's stakeholders.

Version 6.0 of the ISL came into effect on January 1st 2009. The accreditation body and WADA have particular responsibilities in relation to the assessment of the anti-doping laboratory against the WADA ISL and ISL-related Technical Documents. These can be obtained from the WADA web site at www.wada-ama.org.

Areas of the WADA ISL to be covered by the accreditation body

Specific parts of the ISL and the related documents, as detailed below, shall be included in the assessment of laboratories:

- ISL section 4.0 (Process and Requirements for WADA accreditation):
 - Provisions 4.2.1, 4.2.2;
 - Provisions 4.4.1, 4.4.2, 4.4.9, 4.4.10;
 - All of Section 4.5.
- All of Section 5.0 (Application of ISO/IEC 17025 to the Analysis of Urine Doping Control Samples);
- All of Section 6.0 (Application of ISO/IEC 17025 to the Analysis of Blood Doping Control Samples);
- Annex B (Laboratory Code of Ethics):
 - Provision 1.0;
 - Provisions 3.1 and 3.2;
 - Provisions 4.1 – 4.3;
 - Provision 5.
- Technical Documents relevant to the particular anti-doping laboratory.

Areas of the WADA ISL to be covered by WADA

- ISL section 4.0 (Process and Requirements for WADA accreditation):
 - All of section 4.1;
 - Provisions 4.2.2, 4.2.3, 4.2.4, 4.2.5;
 - All of Section 4.3;
 - Provisions 4.4.3 - 4.4.7, 4.4.8, 4.4.11 - 4.4.14
 - All of Section 4.5 (NB: Close collaboration between WADA, the laboratory and the accreditation body is particularly required in preparation for Major Events);
- Annex B (Laboratory Code of Ethics):
 - Provisions 2.0;
 - Provision 4.4 and 4.5.

Reporting on Assessments

The Assessment Summary

The aim of the Assessment Summary is to provide WADA with relevant information on the outcome of the assessment of the anti-doping laboratory (The Assessment Summary is referred to as the “Assessment Summary Report” in the ISL). The accreditation body should provide this summary to WADA in English or French.

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

- The type of visit (re-assessment or surveillance) and the scope of that visit;
- The names of the assessors (indicating the WADA ISL assessor and the roles of the other assessors);
- A list of findings and/or non-conformities identified during the assessment;
- A specific statement that all non-conformities identified have been corrected, and if not, the expected timeframe/deadline for action(s);
- The recommendation on the accreditation of the anti-doping laboratory;
- The recommendation regarding the scope of accreditation and/or any variations in the scope of accreditation;
- A specific statement regarding EQAS results and how these have been handled by the anti-doping laboratory (Emphasis should be given to whether effective corrective actions have been implemented into routine practice by the anti-doping laboratory in the event of unsatisfactory results);
- Any relevant findings of a positive nature that could provide WADA with helpful information on the anti-doping laboratory;
- Information on the next intended visit (expected date and purpose);

Provision of the Full Report on the Assessment

The accreditation body is only required to provide the full report when requested by WADA. Should such a request be made, WADA will also inform the laboratory of this request at that time.

Immediate Notification to WADA

In the event the AB identifies matters of serious concern during the assessment or through other means, the AB should contact WADA immediately by formal letter via email. The reasons for concern should be detailed in the letter.

The AB should also inform the laboratory at this time that it will be contacting WADA and provide the reasons.

WADA External Quality Assessment Scheme (EQAS) Information

WADA accredited laboratories are to make available information on their WADA EQAS performance at each assessment visit. Where difficulty is experienced in obtaining this information the accreditation body should contact WADA.

It should be noted that for initial assessments where there is still a limited number of EQAS samples analyzed by the laboratory, a statement on the performance of the anti-doping laboratory

can also be obtained from WADA. Anti-doping laboratories that are still in the WADA probationary stage are required to take part in multiple (usually four times/year) WADA EQAS rounds. Their results are not however included in the EQAS report or statistical analysis of the broader fully accredited group of anti-doping laboratories.

-----End of ILAC Communication-----