COMMUNICATION FROM 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 communique provides basic information and guidance on the ILAC/WADA collaboration. It is intended for accreditation bodies accrediting World Anti-Doping Agency (WADA) laboratories.

In providing this guidance it is acknowledged that there are some areas that require further consideration and development. Communication with WADA on these issues will therefore need to continue. This will be undertaken through the Technical Accreditation Issues Committee (TAIC). Our early experiences will provide useful information to the TAIC/ WADA collaboration.

Background

ILAC member bodies will be aware, through previous communications from ILAC, of the collaboration between ILAC and the WADA. This collaboration 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. To this end, the following information and recommendations are offered for the consideration of ILAC member bodies dealing with WADA-accredited laboratories. These should be applied as far as is possible at the next scheduled assessment of any WADA laboratory.

ILAC and WADA have had very constructive negotiations to date and the result of an effective collaboration should provide a better service, and greater consistency in standards, for laboratories involved in human doping control. ILAC therefore strongly encourages its member accreditation bodies to participate as far as is possible in this collaboration.

ILAC Recommendations

Areas of the WADA ISL to be Covered during Assessment

The WADA International Standard for Laboratories (ISL) came into force in January 2004. WADA has asked that certain parts of the standard be included in the next scheduled assessment of any WADA-accredited laboratory. The specific areas of the ISL to be incorporated into the routine assessment are detailed below using the clause numbers of the ISL. The ISL can be obtained from the WADA web site <u>www.wada-ama.org</u>, under the Science and Medicine section in Standard for Laboratories. It should be noted that the WADA requirements should fit easily into the routine assessment process, as many of the matters requiring consideration are already part of the assessment.

- Clauses 4.2.5 4.2.9
- Clauses 4.3, 4.3.1, 4.3.2, 4.3.4
- All of Section 5 (Application of ISO/IEC 17025 to the Analysis of Doping Control Samples)
- Annex B Laboratory Code of Ethics
- Annex C List of Technical Documents:

TD2003LCOC - Laboratory Internal Chain of Custody TD2003LDOC - Laboratory Documentation Packages TD2003MRPL - Minimum Required Performance Limits for Detection of Prohibited Substances

TD2003IDCR - Identification Criteria for Qualitative Assays Incorporating Chromatography and Mass Spectrometry

Notification of Laboratories of Collaboration and Reporting Arrangements

It is important that any laboratory you provide accreditation to is informed, prior to the assessment, of the intention to incorporate the WADA ISL into the routine assessment you will be conducting against ISO/IEC 17025.

Assessment Report

The WADA ISL requires compliance with ISO/IEC 17025, as well as WADA's own specific requirements.

There is no need to make a change to your reporting practice other than to include a section dealing with issues specific to the ISL, as described under "Areas of the WADA ISL to be Covered during Assessment". The assessment report should continue to be sent to the laboratory, which is required to submit a copy of the report and documentation of the corrective actions to WADA, according to provisions 6.2.1 and 6.4.7.1 of the ISL.

Advice to WADA on Close-Out of Non-conformities

Accreditation bodies should follow their existing processes for dealing with the close-out of non-conformities identified at assessment. WADA would however like to be informed by the accreditation body when the non-conformities have been closed-out.

Non-conformities identified against the ISL will be dealt with by WADA. Where there is an overlap of ISL and ISO/IEC 17025 nonconformities, then the laboratory will need to advise both the accreditation body and WADA of the action taken.

Use of Trained Assessors

A number of assessors have been trained in assessment against the ISL. WADA requests that attempts be made to include one such assessor on the assessment team.

Information on trained assessors will be available on the WADA <u>www.wada-ama.org</u> and ILAC <u>www.ilac.org</u> web sites.

Technical Updates

WADA will advise accreditation bodies and trained assessors of any changes to the ISL or other relevant WADA documents.

Should you require further information at this time, please feel free to contact, as appropriate, the ILAC Secretariat on <u>ilac@nata.asn.au</u> or WADA on <u>www.wada-ama.org</u>.

ILAC Executive August 2004