Guidelines for harmonization of scopes of ISO/IEC 17025 accreditation of WADA anti-doping laboratories

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ILAC – International Laboratory Accreditation Cooperation

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.
ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement - among Accreditation Bodies (ABs). The data and test results issued by laboratories, and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally via this Arrangement. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of "accredited once, accepted everywhere".
In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.
Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.
Accreditation Bodies that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent implementation of those standards.
Accreditation Bodies having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.
The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at www.publicsectorassurance.org.

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Foreword by the World Anti-Doping Agency

The World Anti-Doping Agency (WADA) is an international independent agency composed and funded equally by the sport movement and governments of the world. WADA's mission is to promote, coordinate and monitor, on an international basis, the fight against doping in sport in all its forms.

To pursue its mission, WADA developed and implemented the World Anti-Doping Program (WADP), which consists of three (3) levels:

- Level 1: World Anti-Doping Code (Code) - the core document of the WADP that harmonizes anti-doping policies, rules and regulations within sport organizations and among public authorities around the world.
- Level 2: International Standards - mandatory documents aimed at bringing harmonization in various technical and operational areas within the WADP.
- Level 3: Models of Best Practice and Guidelines, which are not mandatory documents but offer technical guidance to WADA stakeholders.

The International Standard for Laboratories (ISL) is one of WADA's International Standards. The ISL contains the requirements for the WADA-accredited anti-doping laboratories to enable them to report valid test results and evidentiary data. Laboratory compliance with the ISL rules enables harmonization in analytical testing as well as sets performance criteria for WADA-accredited laboratories worldwide.

WADA's Technical Documents and Technical Letters are considered an integral part of the ISL, and therefore constitute Level-2 mandatory documents. WADA's Technical Documents and Technical Letters supersede any previous publication on a similar topic.

According to the ISL, WADA is responsible for the accreditation and re-accreditation of anti-doping laboratories worldwide, thereby ensuring that they maintain the highest quality standards.

WADA's accreditation requires laboratories to maintain and demonstrate compliance with two international standards: i) ISO/IEC17025 (*General requirements for the competence of testing and calibration laboratories*), which constitutes the basis for WADA's laboratory accreditation, and ii) the ISL, which is a more specific standard applicable to the field of anti-doping testing only.

ILAC full member accreditation bodies (ABs), which are also signatories to the ILAC Mutual Recognition Arrangement (MRA) conduct assessments of WADA anti-doping laboratories using both ISO/IEC 17025 and the ISL.

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PREAMBLE

The *Guidelines for harmonization of scopes of ISO/IEC 17025 accreditation of WADA anti-doping laboratories*[1] have been developed by ILAC and WADA as a joint venture. The members of the ILAC-WADA Liaison Group, the WADA Laboratory Expert Group (LabEG) as well as WADA Science Department have contributed significantly to the development of this document.

PURPOSE

The purpose of this document is to provide ABs that are involved in the ISO/IEC 17025 accreditation of WADA anti-doping laboratories with guidance on the formulation of the scopes of accreditation for these laboratories by taking into account the specificities of the anti-doping field.

Despite the fact that ILAC has a document on the expression of scopes of accreditation (ILAC G18) available, it is recognised that additional guidance regarding the expression of scopes of accreditation in the field of anti-doping testing is needed.

These Guidelines include recommendations on how to adjust the formulation of different types of scopes of accreditation for the WADA anti-doping laboratories and specifically describe the level of flexibility that should be granted to these laboratories.

These Guidelines should also be applied to laboratories in the probationary phase of WADA accreditation when preparing their scope of ISO/IEC 17025 accreditation.

TERMS AND DEFINITIONS [and their source(s)]

For the purposes of these Guidelines, the terms and definitions given in the World Anti-Doping Code, the International Standard for Laboratories (ISL), ISO/IEC Guide 99 VIM and ISO/IEC 17011 apply.

A definition of Flexible Scope of Accreditation is given in the ISL and in ISO/IEC 17011. The two definitions are considered to be complementary (*i.e.* the limitations imposed by either one can be applied simultaneously to the application of flexible scopes in the area defined by the ISL) and are provided below:

Flexible Scope of Accreditation [ISO/IEC 17011:2017]: *scope of accreditation* expressed to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the *conformity assessment body* as confirmed by the *accreditation body.*

NOTE: In these Guidelines “conformity assessment body” should be interpreted as “WADA anti-doping laboratory”

Flexible Scope of Accreditation [ISL]: Status of laboratory accreditation, which allows a WADA anti-doping laboratory or WADA-Approved Laboratory for the ABP to make and implement restricted modifications in the scope of ISO/IEC 17025 accreditation, as applicable, prior to the assessment by the Accreditation Body (please see the ISL for a detailed description of Flexible Scope of Accreditation).

[1] WADA anti-doping laboratories: laboratories that are accredited by WADA in compliance with the ISL and by Accreditation Bodies (which are ILAC full members and signatory to the ILAC MRA) in compliance with ISO/IEC 17025.

1. INTRODUCTION

The scope of ISO/IEC 17025 accreditation is the official statement of activities for which the WADA anti-doping laboratory is accredited. The scope of ISO/IEC 17025 accreditation is issued by the AB, ILAC full member, signatory of the ILAC MRA.

The scope of accreditation is to be described by taking into account the requirements of ISO/IEC 17011, as specified in clause 7.8.3 d) for the scope of accreditation (also referred to as "fixed" scope) and in clause 7.8.4 for the flexible scope of accreditation, when considered.

A flexible scope of accreditation allows a laboratory to improve or modify methods, which are included within its scope of ISO/IEC 17025 accreditation, on the basis of its own validations or verifications. The term "flexible" recognises that an AB will conditionally allow a laboratory to make changes to the methods included within its scope of ISO/IEC 17025 accreditation without the need for an assessment and approval by the AB prior to the laboratory's implementation of these changes. This allowance for flexibility reflects the laboratory's recognized competencies, which are covered by its scope of accreditation.

The flexible system of ISO/IEC 17025 accreditation is to be based on the overall assessment by the AB of the demonstrated competence of the WADA anti-doping laboratory in the implementation of laboratory processes and procedures when following a flexible scope of accreditation system. Accordingly, a WADA anti-doping laboratory may extend its scope, for example, by adding new analytes into an existing analytical method which has already been assessed and accredited.

The flexible scope of ISO/IEC 17025 accreditation is an option supported by WADA under the conditions described herein and should be established for the WADA anti-doping laboratories.

2. SCOPES OF ISO/IEC 17025 ACCREDITATON FOR THE WADA ANTI-DOPING LABORATORIES

As defined in ISO/IEC 17011, all the information contained in the scope of ISO/IEC 17025 accreditation of a WADA anti-doping laboratory is to be made available upon specific request and in accordance with the AB procedure(s) concerning its management of flexible scopes.

Publicly available information:

In accordance with ISO/IEC 17011, the following information on analytical methods included in the scope of ISO/IEC 17025 accreditation should be made publicly available:

- Substance class;
- Purpose of the method;
- Matrix;
- Analytical technique;
- Sample preparation principles;
- Type of method;
- Indication of the type of the scope (flexible or fixed).

Not publicly available information:

It is recognized that in addition to the information contained in the published scope, ABs should have further details available (*e.g.* technical details of the method such as Limits of Detection or Limits of Quantification, specific target analytes) in order to accomplish their assessment responsibilities (please refer to Section 3 Information on Analytical Methods of this document for more details).

This detailed information is not part of the scope of accreditation as defined in ISO/IEC 17011, and therefore should not to be publicly disclosed. This detailed information is to be up-to-date and kept on record in the laboratory and is to be provided to the AB upon request. It is important to note that in some instances, the laboratory can make more detailed information or documents containing sensitive information available to the AB on-site.

3. INFORMATION ON ANALYTICAL METHODS

It is the responsibility of the WADA anti-doping laboratory to maintain a list of analytical methods, including a description of method characteristics and the individual target analytes (please refer to Annex 1 on p.9), and to keep the AB up-to-date on this information.

For each individual prohibited substance, or metabolite or marker of a prohibited substance or prohibited method, the information below is to be included in the information on analytical methods when applicable (see also Annex 1):

- * Unique number or code of the test method (documented procedure);
- * Individual substance (*e.g.* stanozolol): terminology consistent with the Prohibited List in force;
- Class of prohibited substance or prohibited method (e.g. S1, Anabolic Agents; M3, Gene Doping): terminology to be consistent with the Prohibited List in force;
- Purpose of the method:
  - Initial Testing Procedure (ITP); or
  - Qualitative Confirmation Procedure (qualitative CP); or
  - Quantitative Confirmation Procedure (quantitative CP)
- Matrix (terminology consistent with Annex 3);
- Analytical technique (terminology consistent with Annex 4);
- Sample preparation principle (terminology consistent with Annex 5);
- Type of method (standard, non-standard or laboratory-developed)

  Standard methods: for this category, the laboratory's test method is identical to the standard method; or

  Non-standard methods: This category includes non-standard methods, laboratory-developed methods and standard methods validated for use outside their intended scope or otherwise modified. Laboratory-developed test methods are the most applicable for the WADA anti-doping laboratories;

- * MRPL: Minimum Required Performance Level as defined by WADA in the TD MRPL;
- * MU: Measurement Uncertainty (applicable to quantitative confirmation procedures) as estimated during method validation;
- * LOD: Limit of Detection (applicable to initial testing procedures), as estimated during method validation;
- * LOI: Limit of Identification (applicable to qualitative confirmation procedures) as estimated during method validation;
- * LOQ**:** Limit of Quantification (applicable to quantitative confirmation procedures) as estimated during method validation;

  NOTE: The determination of LOQ and estimation of MU also apply, as an exception, to the GC-MS^n initial testing procedure for the markers of the steroid profile.
- * Date of inclusion in the scope of accreditation: either the date on which the substance/method is considered as being included under the flexible scope of ISO/IEC 17025 accreditation by the laboratory in accordance with the AB's procedures, or the date on which the AB accepted the new substance/method as an extension of the accreditation scope;
- Laboratory site: if the laboratory has more than one testing site, then the location where the test methods are performed is necessary or if the test methods are performed as mobile testing, then the term "mobile" is to be indicated, or equivalent expression.

NOTE: An asterisk (*) denotes the information which must **not** be included in the published scope of accreditation.

Boundaries of flexibility:

There are a number of elements in the scopes of accreditation of WADA anti-doping laboratories for which flexibility is not permitted and, therefore, are to be considered as a scope extension. They include the following:

- Class of prohibited substance or prohibited method (*e.g.* S1, Anabolic Agents; M3, Gene Doping);
- Purpose of the method (*e.g.* an analytical method used for initial testing that is adapted to be used as a confirmation procedure);
- Matrix (*e.g.* changing from urine to blood);
- Analytical technique:

  Introduction of a more specific analytical technique, *e.g.* a change from HPLC to UPLC is generally permitted, whereas a change from gas chromatography (GC) to liquid chromatography (LC), or from mass spectrometry (MS) to immunoassay, should not be subject to flexibility.
- Sample preparation principle:

A modification of the sample preparation principle (e.g. the physical separation principle from ultrafiltration to immunopurification, or from Liquid-liquid Extraction to Solid Phase Extraction) should not be subject to flexibility.

- Type of method (*e.g.* changing from a standard method to a non-standard method);
- WADA-specific analytical testing procedures: new test methods and analytical testing procedures requiring specific WADA approval prior to application to anti-doping samples (see ISL).

  NOTE: For these methods, flexibility is not allowed for their initial inclusion within the scope of ISO/IEC 17025 accreditation, even if the addition of the proposed method would fall within the boundaries of flexibility allowed by this document. An assessment of these new or WADA-specific methods by the AB is required prior to the method's inclusion in the scope of ISO/IEC 17025 accreditation. However, once included within the scope, limited changes to these methods can be made within the boundaries of flexibility allowed by this document. Nonetheless, this flexibility does not allow the introduction within these procedures of new analytes for which specific compliance decision criteria are needed and are not defined yet in an applicable Technical Document (e.g. new target compound(s) for GC/C/IRMS analysis).

  The list of WADA-specific Analytical Testing Procedures will be made available to the AB. Assessment of WADA-specific methods by the AB is required prior to the method being included in the scope of accreditation.

A flexible scope of ISO/IEC 17025 accreditation is needed for WADA anti-doping laboratories to be able to rapidly introduce a test for newly identified prohibited substances or prohibited methods and to comply with variations of threshold concentrations and MRPLs.

Examples of permitted flexibility include:

- Addition of new substances (target analytes) within an existing analytical method;
- Modification of method performance characteristics (dynamic range, LOD, LOQ, LOI, MU, etc.);
- Modifying data acquisition parameters of an accredited analytical method (*e.g.* variations in chromatography conditions: introduction of new or change of diagnostic ions/transitions; increase of run time; adjustment of elution gradient; change of injection volume);
- Modifying elements of a sample preparation procedure already included within the scope (*e.g.* small variations in hydrolysis conditions such as time of hydrolysis, clean-up steps; initial sample volume; sample dilution);
- Linking sample preparation principles, which are within the scope of accreditation, to additional analytical techniques. This will, however, be dependent on the laboratory's capability to demonstrate, through its method validation, that the application of an existing sample preparation principle to a new/different analytical technique results in an analytical method that is fit-for-purpose. Adding a new sample preparation principle will require a scope extension request;

NOTE: The sample preparation principles in the scope of accreditation are considered independent of the analytical techniques.

- Developing new analytical testing procedure(s) that involve technology already included within the scope (except for WADA-specific procedures);

In situations when, following WADA's revision of the Prohibited List, substances are moved from one substance class to another, or if the naming of the substance class or prohibited method category is changed (*e.g.* P2 becomes P1), any resulting change in the content of the scope of accreditation will be considered as editorial, and the relevant change should be made by the AB without the need for additional assessment by the AB.

4. SCOPE EXTENSIONS

For the cases when the new or modified Analytical Testing Procedure(s) (proposed by the WADA anti-doping laboratory for the inclusion into their scope of accreditation) are not within the flexibility granted by the AB, then the laboratory shall request a scope extension from its AB. This scope extension should be dealt with by each AB according to its normal scope extension procedure.

5. COMMON TERMINOLOGY

The consistency of terminology used by ABs in the description of scopes of accreditation is essential to achieve a harmonized approach in the formulation of the scopes. Annexes 1- 5 below contain the terminology to be used for the scopes of ISO/IEC 17025 accreditation of the WADA-accredited laboratories.

6. REFERENCES

For all references the latest edition of the document (including any amendments) applies. The effective versions of the WADA Anti-Doping Code, the WADA International Standard for Laboratories, and related WADA Technical Documents and Laboratory Guidelines are available at https://www.wada-ama.org/en/what-we-do/science-medical/laboratories.

- ISO/IEC 17011, Conformity assessment - Requirements for ABs accrediting conformity assessment bodies
- JCGM 200 (ISO/IEC Guide 99), International vocabulary of metrology – Basic and general concepts and associated terms (VIM)
- WADA World Anti-Doping Code (Code)
- WADA International Standard for Laboratories (ISL)
- WADA List of Prohibited Substances (Prohibited List)
- ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories
- ISO 15189, Medical laboratories – Requirements for quality and competence
- ILAC G18, Guideline for the formulation of scopes of accreditation for laboratories.

7. LIST OF ANNEXES

ANNEX 1: List of analytical methods (proposed model)

ANNEX 2: List of classes/subclasses of substances (WADA Prohibited List in effect).

ANNEX 3: List of matrices

ANNEX 4: List of analytical techniques

ANNEX 5: List of sample preparation principles

ANNEX 1: List of analytical methods with method performance characteristics and individual analytes covered

(* Information **not** included in the published scope of accreditation)

Method code *	Individual Substance *	Substance class [a]	Purpose of the method (ITP, qualitative CP, quantitative CP)	Matrix [b]	Analytical technique [c]	Sample Preparation Principle [d]	Type of method (Standard, Lab-developed)	MRPL*	LOD [e] *	LOQ [e] *	MU [e] *	LOI [e] *	Accreditation date *	Lab. Site	Flexible extension Y/N *

a: According to the WADA Prohibited List in effect (Annex 2)
b: According to Annex 3
c: According to Annex 4
d: According to Annex 5
e: as determined by the Laboratory during method validation

ANNEX 2: List of classes/subclasses of substances

- According to the WADA Prohibited List in force

ANNEX 3: List of matrices (human)

- Urine
- Whole blood (venous, capillary blood)
- Plasma
- Serum
- Saliva
- Keratin fibres (*e.g.* Hair)
- Other matrices may be considered if deemed necessary. They should be reported to the ILAC WADA Liaison Group by the AB.

NOTE: Urine, whole blood and blood fluids (plasma and serum) are the common matrices used by WADA anti-doping laboratories in routine analyses.

ANNEX 4: List of analytical techniques used in anti-doping laboratories

- Affinity-binding assays (*e.g.* immunoassays)
- Capillary LC
- Capillary electrophoresis
- Chiral separation
- Flow cytometry
- GC
- GC/C/IRMS
- GC/GC
- GC-HRMS^n (n≥1)
- GC-MS^n (n≥1)
- GC-NPD
- Gel electrophoresis (e.g. IEF-PAGE, SDS-PAGE, SAR-PAGE)
- Immunoblotting
- LC
- LC/LC
- LC-HRMS^n (n≥1)
- LC-MS^n (n≥1)
- Nano-LC
- PCR
- Physico-chemical analysis
- Potentiometry
- Refractometry
- Spectrophotometry
- Spectroscopy
- Supercritical fluid chromatography (SFC)

Other analytical techniques may be considered if deemed necessary. They should be reported to the ILAC WADA Liaison Group by the AB.

ANNEX 5: List of sample preparation principles

- Chemical hydrolysis
- Derivatization
- Dilute and shoot
- Enzymatic digestion
- Enzymatic hydrolysis
- Immunopurification
- Liquid-liquid extraction (LLE)
- Precipitation
- Solid phase extraction (SPE)
- Supported liquid extraction (SLE)
- Ultrafiltration

Other preparation techniques may be considered if deemed necessary. They should be reported to the ILAC-WADA Liaison Group by the AB.