Specific provisions for the EN ISO/IEC 17025 accreditation of WADA anti-doping laboratories

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DOCUMENT HISTORY

Revision and date of approval	Reason for revision	Impact of revision
0 **CC 26.04.2022**	New document	

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1. OBJECTIVES AND REFERENCES TO NORMATIVE DOCUMENTS

Belgian anti-doping laboratories applying for recognition by WADA (World Anti-doping Agency) are required to maintain a BELAC accreditation according to the requirements of EN ISO/IEC 17025:2017 complemented with the WADA's International Standard for Laboratories (ISL) and associated documents.

WADA, as owner of this specific conformity assessment scheme and after close cooperation with ILAC, has defined complementary requirements applicable to the accreditation bodies, in this case BELAC.

The objective of this BELAC 2-405 WADA document is to summarize the specific requirements applicable to both BELAC and its anti-doping accredited laboratories .

2. RECIPIENTS

- Members of the Coordination Commission
- Members of the Accreditation Board
- Accreditation secretariat
- Assessors
- Accredited WADA anti-doping laboratories

3. DEFINITIONS AND/OR INTERPRETATIONS OF TERMS

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

3.2 World Anti-Doping Program (WADP): A program developed and implemented by WADA to achieve its mission. This program includes the following 3 instruments::

3.2.1 Level 1 : World Anti-Doping Code (Code): The Code is a core document that provides the framework for anti-doping policies, rules, and regulations within sport organizations and among public authorities.

3.2.2 Level 2 : International Standards and technical documents : mandatory documents aiming to bring harmonization within the different technical and operational areas related to WADP

3.2.3 Level 3 : Models of Best Practice and Guidelines: non-mandatory documents aiming to provide technical support to WADA stakeholders.

3.3 International Standard for Laboratories (ISL): one of the WADA's International Standards. The ISL contains the requirements that WADA accredited laboratories must meet with regard to reporting valid test results and evidence-based data.

3.4 Confirmation Procedure (CP): An Analytical Testing Procedure that has the purpose of confirming the presence and/or, when applicable, confirming the concentration/ratio/score nd/or establishing the origin (exogenous or endogenous) of one or more specific Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method in a Sample.

3.5 Initial Testing Procedure (ITP): An Analytical Testing Procedure whose purpose is to identify those Samples which may contain a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method or an elevated quantity of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

3.6 Minimum Required Performance Level (MRPL): Minimum analytical criterion of Laboratory technical performance established by WADA. Minimum concentration at which a Laboratory is expected to consistently detect and confirm a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Prohibited Method in the routine daily operation of the Laboratory. Individual Laboratories may and are expected to achieve better performance [see Technical Document on Minimum Required Performance Levels (TD MRPL)].

3.7 Laboratory Internal Chain of Custody: Documentation maintained within the Laboratory to record the chronological traceability of custody (by Person(s) or upon storage) and actions performed on the Sample and any Aliquot of the Sample taken for Analytical Testing.

4. DESCRIPTION OF THE ACTIVITY

4.1. Identification of the activity	WADA
4.2. Type(s) of conformity assessment bodies and accreditation standard	Analyses within the framework of anti-doping control according to the WADA program Accreditation as testing laboratory according to EN ISO 17025:2017
4.3. Classification according to BELAC 6-017	2.4.5
4.4. Reference document(s) for the activity, including the publication date or a version number	- International Standard for Laboratories (ISL) version 11.0 of January 2021 , with reference to o Technical Documents (mandatory) o Technical Letters (mandatory) o Laboratory Guidelines (not mandatory) o Technical Notes (not mandatory) (remark : technical notes are provided to laboratories only and are not published on WADA's website) - ILAC-G29:06/2020 Guidelines for Harmonization of Scopes of EN ISO/IEC 17025 Accreditation of WADA anti-doping Laboratories - ILAC-WADA 3rd Communiqué (01.04.2021) - WADA-ILAC Memorandum of Understanding (MoU) (2021)
4.5. Body responsible for the development and maintenance of the activity	WADA

5. SPECIFIC PROVISIONS APPLICABLE TO THE WADA ANTI-DOPING LABORATORIES

The ISL requires that the EN 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 BELAC takes also into account the ISL, its related Technical Documents (TDs) and Technical Letters (TLs), in addition to EN ISO/IEC 17025, when performing an assessment of the WADA anti-doping laboratories.

Consequently, during a BELAC assessment specific attention will be paid to verify compliance with the specific requirements. All relevant information related to the evaluation of the fulfilment of these specific requirements shall be included in the assessment report.

5.1 WADA complementary requirements for the application of EN ISO/IEC 17025:2017: ISL Clauses 5, 6, 7 and Annex A (Code of Ethics)

The correspondence table below is limited to the list of topics referred to in ISL (clauses 5, 6 and 7) and in Annex A (Code of Ethics) that complement the requirements of EN ISO/IEC 17025: 2017 and are applicable to all anti-doping laboratories. The full text of ISL has to be taken into account .

In case a Laboratory is preparing for a Major Event, e.g. Olympic Games, the requirements of Annex B (Accreditation Requirements for Major Events) will be taken into account as well.

EN ISO/IEC 17025:2017	**ISL 2021 and/or Code of Ethics**
Clause 4.1 Impartiality	ISL 4.4.2.4 Laboratory independence and impartiality
Clause 4.2 Confidentiality	ISL 5.2.3.4 Confidentiality of Data, Information and Operations ISL 5.3.8.3 Confidentiality of the Analytical Data and Athlete's Identity ISL Annex A point 1: Confidentiality
Clause 5.3 Activities of the laboratory	ISL Annex A point 2: Research in support of Doping Control ISL Annex A point 3: - Analysis 3.0 to 3.4:- Activities that undermine or are detrimental to the World Anti-Doping Program - Sharing of Knowledge: 3.5
Clause 6.2 Personnel	ISL 5.2.2 Laboratory Personnel : - 5.2.2.1 Laboratory Director - 5.2.2.2 Laboratory Quality Manager - 5.2.2.3 Laboratory Certifying Scientists - 5.2.2.4 Laboratory Supervisory Personnel ISL Annex A points 4 and 5: Deontology rules for laboratory's personnel and sanctions in case of breach
Clause 6.3	ISL 5.2.3 Laboratory Facilities and Environmental Conditions

Facilities and Environmental Conditions	- 5.2.3.1 Laboratory Facilities - 5.2.3.2 Relocation of Laboratory Facilities - 5.2.3.3 Environmental control
Clause 6.4 Equipment	ISL 5.2.4 Laboratory Equipment
Clause 6.5 Metrological traceability	ISL 5.2.5 Metrological traceability - 5.2.5.1 Reference Materials - 5.2.5.2 Reference collections
Clause 6.6 Externally provided products and services	ISL 5.2.6 Subcontracting of analysis ISL 5.2.7 Purchasing of Services and Supplies
Clause 7.1 Review of requests, tenders and contracts – cooperation with customers or their representatives	ISL 5.4.5 Cooperation with customers and with WADA
Clause 7.2 Selection, verification and validation of methods	ISL 5.3.5 Selection and Validation of Analytical Testing Procedures - 5.3.5.1 Validation of Analytical Testing Procedures for Non-Threshold Substances - 5.3.5.2 Validation of Analytical Testing Procedures for Threshold Substances ISL 5.3.6 Sample analysis - 5.3.6.1 Application of Initial Testing Procedure - 5.3.6.2 Application of Conformation Procedures - 5.3.6.3 Further Analysis - 5.3.6.4 Alternative Biological Matrices
Clause 7.4 Handling of test items	ISL 5.3.2 Reception, Registration and Handling of samples ISL 5.3.3 Acceptance of Samples for analysis - 5.3.3.1 Samples with Irregularities - 5.3.3.2 Sample Splitting Procedure ISL 5.3.4 Initial Storage and Sample Aliquoting for Analysis - 5.3.4.1 Urine samples - 5.3.4.2 Blood samples ISL 5.3.11 Storage of Samples - 5.3.11.1 Storage of Urine Samples - 5.3.11.2 Storage of Blood Samples - 5.3.11.3 Long-term Storage of Samples ISL 5.3.12 Secondary Use or Disposal of Samples and Aliquots
Clause 7.5 Technical records	ISL 5.3.8.2 Traceability of Results and Documentation ISL 5.4.4 Control and storage of technical records ISL 5.3 Laboratory paper or electronic Internal Chain of Custody in compliance with Technical document TD LCOC
Clause 7.7 Ensuring the validity of results	ISL 5.3.7 Assuring the Validity of Analytical Results ISL 5.3.8 Results Management - 5.3.8.1 Review of Results - 5.3.8.2 Traceability of Results and Documentation ISL 6.3 + 7 WADA External Quality Assessment Schemes (EQAS) THIRD ILAC-WADA COMMUNIQUE 5.5 : 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.
Clause 7.8 Reporting of results	ISL 5.3.8.4 Reporting Test Results
Clause 7.9 Complaints	ISL 5.3.10 Complaints
Clause 7.10 Nonconforming work	ISL 5.3.9 Control of Nonconformities in Analytical Testing
Clause 7.11 Control of Data and Information management	ISL 5.2.3.5 Control and Security of Electronic Data and Information
Clause 8.3 Management of documentation	ISL 5.4.3 Document control
Clause 8.4 Management of records	ISL 5.4.4 Control and storage of technical records

5.2 Other complementary requirements or guidelines

- Technical Documents (mandatory - available from WADA webpage)
- Technical Letters (mandatory - available from WADA webpage)
- Technical Guidelines (not mandatory - available from WADA webpage)
- Technical Notes (not mandatory

6. SPECIFIC PROVISIONS APPLICABLE TO BELAC

6.1 BELAC 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 BELAC 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 BELAC attention;

c) When circumstances allow, invite, as observer(s), WADA representative(s) to BELAC assessment(s);

d) Incorporate the monitoring of compliance with the WADA ISL, TDs and TLs into the routine assessments of WADA anti-doping laboratories. WADA Laboratory Guidelines (LGs), although not mandatory, should also be considered as they offer recommendations of best practice;

e) In accordance with BELAC 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);

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 BELAC 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 (see under points 5.1 and 5.2 of the ILAC-WADA 3d Communiqué 01.01.2021 for more information on the content of the Assessment Summary). Based on an agreement between the laboratory and BELAC, BELAC should provide the Assessment Summary; however, the laboratory may also take responsibility to forward the Assessment Summary to WADA;

> "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 EN ISO/IEC 17025 accreditation and/or any changes to the EN 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 BELAC 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."

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 EN ISO/IEC 17025 accreditation status of the laboratory. BELAC is to inform the laboratory that it will be contacting WADA and the reason(s);

2. when a laboratory's EN 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 EN ISO/IEC 17025 accredited status.

THIRD ILAC-WADA COMMUNIQUE 5.5 : "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"

6.2 BELAC 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 WADA ISL-trained assessors employed by or under contract with BELAC maintain their competence;

c) Inform WADA when a WADA ISL-trained assessor is no longer employed by or under contract with BELAC and propose alternative candidate(s) to undergo ISL training at the next training opportunity.

7. DESCRIPTION OF THE ACCREDITATION SCOPE:

7.1 Accreditation with fixed scope

In case the laboratory applies for a fixed scope (e.g. for routine analyses), the following information will be mentioned in the BELAC scope:

- A unique code number for the test method (according to a documented procedure);
- The specifically concerned substance + Substance class to which it belongs (according to the WADA Prohibited List in effect);
- Purpose of the method (Initial Testing Procedure (ITP), Qualitative Confirmation Procedure (CP) or quantitative Confirmation Procedure (CP));
- Matrix (according to ILAC G29 Annex 3);
- Analytical technique (according to ILAC G29 Annex 4);
- Sample preparation principle (according to ILAC G29 Annex 5);
- Type of method (standard, non-standard or laboratory developed);
- Laboratory site if the laboratory has more than one testing site – if tests are performed as mobile testing, this shall be made clear as well.

In addition to the information contained in the published scope, the accredited laboratories are expected to maintain updated the following additional information (whenever relevant) and to keep it available to BELAC on request or during assessments :

- 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.

7.2 Accreditation with flexible scope

The flexible scope of EN ISO/IEC 17025 accreditation is an option supported by WADA under the conditions described below. The flexible scope within an EN ISO/IEC 17025 accreditation is to be based on the overall assessment by BELAC of the demonstrated competence of the WADA anti-doping laboratory in the implementation of laboratory processes and procedures.

Within the framework of a flexible scope, 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.

In addition to the requirements included in BELAC 2-101 for the formulation and evaluation of the accreditation scope of a testing laboratory, the requirements mentioned below apply for a flexible scope of WADA anti-doping laboratories.

In case of a flexible scope, the following information will be mentioned in the BELAC scope:

- Substance class (according to the WADA Prohibited List in effect);

- Purpose of the method (Initial Testing Procedure (ITP), Qualitative Confirmation Procedure (CP) or quantitative Confirmation Procedure (CP));
- Matrix (according to ILAC G29 Annex 3);
- Analytical technique (according to ILAC G29 Annex 4);
- Sample preparation principle (according to ILAC G29 Annex 5);
- Type of method;
- Laboratory site if the laboratory has more than one testing site – if tests are performed as mobile testing, this shall be made clear as well.

The laboratory shall keep an up-to-date detailed list, containing the following information for each analytical method and each individual prohibited substance or metabolite or marker (see annex 1 in ILAC G29):

- ❖ A unique code number for the test method (according to a documented procedure)
- ❖ The specifically concerned substance
- ❖ Minimum Required Performance Level (MRPL)
- ❖ Measurement uncertainty (MU)
- ❖ Detection limit (LOD)
- ❖ Identification limit (LOI)
- ❖ Quantification limit (LOQ)
- ❖ Date of integration in the accreditation scope

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

Remark : 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 BELAC without the need for additional assessment .

Boundaries of flexibility: the following elements of the accreditation scope are <u>not eligible for flexibility</u> and a formal application request at BELAC for extension of the scope is required:

- Class of prohibited substance or method;
- Purpose of the method;
- Matrix;
- Analytical technique (exception: implementation of a more specific analytical technique such as UPLC in place of HPLC);
- Sample preparation principle;
- Type of method (e.g. changing from a standard method to a non-standard method);
- WADA-specific analytical testing procedures (new test methods in the field of anti-doping analysis and specific analytical testing procedures requiring specific WADA approval prior to application to anti-doping samples) even if the proposed method would fall within the boundaries of flexibility). 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).
