

INTERNATIONAL STANDARD FOR LABORATORIES (ISL) Consultation - Second consultation phase

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PART ONE: INTRODUCTION, CODE PROVISIONS AND DEFINITIONS (4)

Doping Authority Netherlands

Olivier de Hon, Chief Operating Officer (Netherlands)
NADO - NADO

SUBMITTED

Generally speaking, the new draft is an improvement as it can be expected to strengthen the work of laboratories. We specifically acknowledge the merger of the previous sections 5 (analysis in urine) and 6 (analysis in blood), the reflection of recent changes in ISO accreditation, and the enhanced EQAS scheme.

Conseil supérieur des sports

Matheo TRIKI, Sportif Rugby (Espagne)
WADA - Others

SUBMITTED

1.0 Introduction, Scope and References

1.1 The ISL and the World Anti-Doping Program

The main elements are:

- the Code (Level 1),
- International Standards (Level 2), and
- Models of Best Practice and Guidelines (Level 3).

1.2 WADA Laboratory Standards

1.2.1 Technical Documents

1.2.2 Technical Letters

1.2.3 Laboratory Guidelines

1.2.4 Technical Notes

1.3 Sample Analysis

Sample analysis is part of the Analytical Testing process and involves the detection, identification, and in some cases demonstration of the presence above a Threshold of Prohibited Substance(s) and/or their Metabolite(s), or

Marker(s) of Use of Prohibited Substances or Prohibited Methods in human biological fluids or tissues.

1.4 Laboratory Accreditation Framework and Laboratory Approval for the ABP

The Laboratory accreditation framework consists of two main elements: Part Two of the ISL (Laboratory accreditation requirements and operating standards) and Part Three (the Annexes).

2.0 Code Provisions

The following Articles in the Code are addressed in the ISL:

■

Code Art. 2 ANTI-DOPING RULE VIOLATIONS

■

Code Art. 3 PROOF OF DOPING

■

Code Art. 4 THE PROHIBITED LIST

■

Code Art. 6 ANALYSIS OF SAMPLES

■

Code Art. 10 SANCTIONS ON INDIVIDUALS

■

Code Art. 13 APPEALS

■

Code Art. 14 CONFIDENTIALITY AND REPORTING

3.0 Terms and Definitions 3.1 Code defined terms

ADAMS

Adverse Analytical Finding

Adverse Passport Finding

Anti-Doping Organization

Athlete

3.2 ISL Defined Terms

Adaptive Model

Aliquot Analyte

Analytical Method Analytical Testing

Analytical Testing Procedure

Analytical Testing Restriction

Athlete Passport Management Unit (APMU)

Bias (b)
Certified Reference

Material (CRM)

3.3 International Standard for Testing and Investigations (ISTI) Defined Terms

Results Management Authority

Sample Collection Authority

Sample Collection Session

Suitable Volume of Urine for Analysis

Test Distribution Plan

Testing Authority

Seibersdorf Laboratories

SUBMITTED

Guenter Gmeiner, Lab Director (Austria)
Other - WADA-accredited Laboratories

Generally spoken is the ISL the main document for laboratory operations and regulates anti-doping analyses based on the ISO 17025 standard. Consequently care has to be taken in sections which contradict to the ISO standard. Harmonization is one of the important goals. Therefore the final draft of the ISL has to be reviewed and commented by ILAC and adapted in case of inconsistencies. Before passing the final version to the WADA Exco a statement from ILAC shall be provided to the Exco members.

NMI - ASDTL

SUBMITTED

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

This submission is provided on behalf of the the World Association of Anti-Doping Scientists (WAADS). The laboratories have consistently raised concerns with certain aspects of the ISL during stakeholder reviews, WAADS has limited the comments during this consultation process in order to assure that the most critical aspects from our point of view can be addressed.

The two main points

1. Clause 4.4.1 shall be removed.

2. Section 6 - WADA External Quality Assessment Scheme (EQAS) and Section 7 - Evaluation of laboratory EQAS and routine analytical testing performance. These sections need to be reviewed and fundamental changes made to achieve consistency, transparency and fair decision making in relation to the suspension and revocation processes.

The new ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories was released in October 2017 with an implementation date of October 2020. All WADA laboratories are accredited to ISO/IEC 17025 as well as the ISL; these two standards work hand in hand and must complement each other in order to have an effective accreditation system. The new ISO/IEC 17025:2017 highlights the requirements risk-based thinking and thus implementing appropriate processes to address risks. Risk assessment and treatment planning is the appropriate management system which must be implemented for the ISL in relation to the suspension and revocation processes. The suspension or revocation of accreditation shall directly relate to the capability of a laboratory to report valid test results and to comply with the requirements set out in the standards.

Taking into consideration the implementation of the new 'ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories' the final draft of the ISL shall be reviewed by International Laboratory Accreditation Cooperation (ILAC) to ensure there are no conflicts with between the ISL and ISO/IEC 17025:2017. WADA laboratories must hold accreditation to ISO/IEC 17025:2017 as such the laboratories can not be in conflict with this standard because of requirements stated in the ISL. The final version of the ISL as presented to the WADA ExCO shall include a statement from ILAC to assure the accreditation of WADA laboratories is not jeopardised.

As a general comment it should be added that many modifications seem to relate to the perception that there are problems with the standards of quality the laboratories are achieving. The modifications in large attempt to address this perceived problem by introducing more stringent penalty system but over the last three years of suspensions and revocations it has been demonstrated the system is not working, as such, it would be most valuable for the WADA to conduct a root cause analysis. Everyone, including the WADA and all other stakeholders, would like to see the WADA laboratories not facing the continued problems.

The staff in the laboratories are frustrated and down trodden, in general no one come to work wanting or aiming to do a bad job. Many of us come to work because we genuinely believe in "Play True" but it must be applied to all aspects of the anti-doping system, including the laboratories.

The core values represented by WADA, integrity, accountability and excellence, are those held by the WADA accredited laboratories. It is time for us to collaboratively reflect and gain better outcomes for all the stakeholders. The WADA accredited laboratories are a key part of the worldwide movement for doping-free sport.

3.0 Terms and Definitions

3.2 ISL Defined Terms (2)

International Testing Agency

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

SUBMITTED

In relation to the definition of Confirmation Procedure, consider that when confirming a steroid profile, the purpose is not to confirming the presence of a prohibited substance. The endogenous profile must just be re-analysed to exclude instances such as urine contamination, laboratory's mistakes, etc.

In relation to the definition of Negative Finding, consider the following amendment: "(...) concludes that no Prohibited Substance(s) or its Metabolite(s) or Marker(s) or evidence of the Use of a Prohibited Method(s), included in the requested Analytical Testing menu, were found in a Sample **at the time of the Initial Analysis and applying the accredited methods used in the concerned Laboratory.**"

In relation to the definition of Independent Witness, consider clarifying the concept of (functional) independence, given the entitlement of the witness to an indemnification by the TA/laboratory.

The terminology "false negative" should be used more accurately and needs re-adaptation. For purposes of illustration, some samples re-analysed were initially reported negative; however, those cannot be considered as false negatives. Laboratories have different detection limits but this shall not mean that a false negative, within the meaning used across the Standard, is produced.

Swiss Laboratory for Doping Analyses

Tiia Kuuranne, Director (Switzerland)
Other - WADA-accredited Laboratories

SUBMITTED

Laboratory Expert Group is not defined as an ISL term. Please, add.

Please, consider addition of "Certificate of Analysis" (as per TD2017LDOC) as an ISL defined term.

PART TWO: LABORATORY ACCREDITATION REQUIREMENTS AND OPERATING STANDARDS (2)**Conseil supérieur des sports**

Matheo TRIKI, Sportif Rugby (Espagne)
WADA - Others

SUBMITTED

1.

Important modifications and updates have been introduced to Section 1

2.

The section of ISL definitions has been revised to include new metrological and method validation terms;

3.

Important modifications and updates have been introduced to Section 4

4.

A new Section 5 (Analysis of Samples) has been created, where the previous Sections 5 (analysis in urine) and 6 (analysis in blood) have been merged.

5.

The previous Annex A – EQAS has been split into two new Sections: Section 6 (EQAS Program) and Section 7 (Laboratory Performance Evaluation), and requirements have been thoroughly revised.

Institute for Dopinganalysis and Sportsbiochemistry

Kai Weigel, QMB (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

4.4.1 Payment of Host Country's Annual Financial Contribution to WADA

For a Laboratory to maintain its *WADA* accreditation status, its host country shall pay its annual financial contribution to *WADA* in a timely manner, as determined by *WADA*.

Contradiction to 4.1.7 Laboratory Independence and Impartiality.

4.0 Process and Requirements for WADA Laboratory Accreditation (2)

Gouvernement du Canada

Francois Allaire, Agent Principal de Programme (Canada)
Public Authorities - Government

SUBMITTED

International Standard for Laboratories – Article 4.4.1

The Government of Canada strongly suggests to remove Article 4.4.1 on payment of host country's annual financial contribution to WADA for a Laboratory to maintain its accreditation status, as it conflicts with the spirit and intent of Articles 4.17 and 4.4.3 on laboratory independence and impartiality. The payment of a host country's annual contribution to WADA falls outside the jurisdiction or control of any WADA-accredited laboratory and as such should not be linked to its accreditation, as it contravenes its necessary independence and operational integrity.

Swiss Laboratory for Doping Analyses

Tiia Kuuranne, Director (Switzerland)
Other - WADA-accredited Laboratories

SUBMITTED

Please, consider addition of conditions to manage a process where an accredited/approved laboratory voluntarily withdraws the WADA-mandate.

4.1 Applying for a WADA Laboratory Accreditation (1)

Swedish Sports Confederation

Tommy Forsgren, Results Mangement Manager (Sweden)
NADO - NADO

SUBMITTED

The new clause: Adressed in both 4.1.1 and 4.4.1 Payment of Host Country's Annual Financial

Contribution to *WADA*

"For a Laboratory to maintain its *WADA* accreditation status, its host country shall pay its annual financial contribution to *WADA* in a timely manner, as determined by *WADA*."

We do not agree with this clause as it is contra productive to the laboratory's independence. The laboratory's main task is to report excellent quality test results independent of any political factors.

4.1.2 Submitting Initial Application Form (1)

Norwegian Doping Control Laboratory

Yvette Dehnes, Laboratory Director (Norway)
Other - WADA-accredited Laboratories

SUBMITTED

"An applicant laboratory may only submit an application if the following essential conditions are fulfilled in its host country:

- The payment of the annual financial contributions to *WADA*."

Comment: This clause must be removed, because:

Laboratory independence is jeopardised as clause 4.4.1 provides the host government/country with a direct leverage over the laboratory operation.

The laboratory independence needs to be assured by not linking the ongoing accreditation to Government/country financial contribution to *WADA*!

This clause forms no part of the quality management of a laboratory! The main purpose of IS for Laboratories is to ensure that Laboratories report valid test results and evidentiary data and to achieve, as much as possible, harmonization in Analytical Testing from all Laboratories.

4.1.7 Laboratory Independence and Impartiality (1)

UCLA Olympic Analytical Laboratory

Tim Sobolevsky, Senior Scientist (USA)
Other - WADA-accredited Laboratories

SUBMITTED

In the context of administrative and operational independence, it is strongly suggested to explicitly spell out "the laboratory host organization" in addition to "anti-doping, sport and other political organizations" or "any Person" so that the laboratory has leverage over its host organization.

4.2 Preparing for WADA Laboratory Accreditation

4.2.1 Pre-Probationary Test and On-Site Assessment (1)

Swiss Laboratory for Doping Analyses

Tiia Kuuranne, Director (Switzerland)
Other - WADA-accredited Laboratories

SUBMITTED

4.1.2 Submitting Initial Application Form

- ~~The payment of the nation's financial contributions to *WADA*.~~

Contradictory to §4.1.7 about lab independency. Taking into account the independence of the laboratories, this obligation and the connection with direct implications to the accreditation is not acceptable and should be removed.

4.4 Maintaining WADA Accreditation (2)

Anti Doping Denmark

Jesper Frigast LARSEN, Legal Manager (Denmark)
NADO - NADO

SUBMITTED

DoCoLab - UGent

Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

SUBMITTED

In this part, information is missing to what needs to happen if a Laboratory is revoked. How will the samples and records be kept for ten years? Who takes care of this, who maintains this, etc.

4.4.1 Payment of Host Country's Annual Financial Contribution to WADA (19)

Department of Health - National Integrity of Sport Unit

Luke Janeczko, Policy Officer (Australia)

Public Authorities - Government

SUBMITTED

The proposed linking of a nation's annual payment to WADA to laboratory accreditation is not supported. This contradicts the principle that an accredited laboratory should operate independently of government. It is also discriminatory as less than 30 countries, including Australia, host WADA-accredited laboratories.

Australia, and Oceania, have previously opposed this proposal.

Anti Doping Denmark

Jesper Frigast LARSEN, Legal Manager (Denmark)

NADO - NADO

SUBMITTED

The proposed article 4.4.1 reads: "Payment of Host Country's Annual Financial Contribution to WADA. For a Laboratory to maintain its WADA accreditation status, its host country shall pay its annual financial contribution to WADA in a timely manner, as determined by WADA."

We are of the opinion that this proposed article somewhat contradicts the proposed articles 4.1.7 and 4.4.4 and the principle of laboratory independence and impartiality.

We appreciate that countries should pay their financial contributions to WADA in a timely manner, but far from every country has a WADA accredited laboratory and the accreditation of a well-functioning and operationally independent lab should not be endangered by a possible conflict between the country and WADA about payment.

In particular, it should be stressed that each accredited lab typically also serves as lab for NADOs from other countries (whose governments pay their WADA dues!) and other ADOs, and it would have severely logistical and financial consequences for the work and operations of these ADOs if an accredited lab were to lose its accreditation due to the government of its host country not paying its dues to WADA.

We therefore propose that the proposed art. 4.4.1 is deleted.

NADA

Regine Reiser, Result Management (Deutschland)

NADO - NADO

SUBMITTED

For a Laboratory to maintain its WADA accreditation status, its host country shall pay its annual financial contribution to WADA in a timely manner, as determined by WADA.'

This clause shall be removed as it forms no part of the quality management of a laboratory. The main purpose of IS for Laboratories is to ensure that Laboratories report valid test results and evidentiary data and to achieve, as much as possible, harmonization in Analytical Testing from all Laboratories.

Laboratory independence is jeopardized as clause 4.4.1 provided the host government/country with a direct leverage over the laboratory operation. The laboratory independence needs to be assured by not linking the ongoing accreditation to Government/country.

Antidoping Switzerland

Ernst König, CEO (Switzerland)
NADO - NADO

SUBMITTED

Removal of clause 4.4.1.

Laboratory independence is jeopardised as clause 4.4.1 provides the host government/country with a direct leverage over the laboratory operation. The laboratory independence needs to be assured by not linking the ongoing accreditation to Government/country financial contribution to WADA.

Sport Ireland

Siobhan Leonard, Director of Anti-Doping & Ethics (Ireland)
NADO - NADO

SUBMITTED

This clause shall be removed as it forms no part of the quality management of a laboratory. The main purpose of the ISL is to ensure that Laboratories report valid test results and evidentiary data and to achieve, as much as possible, harmonization in Analytical Testing from all Laboratories.

Laboratory independence is jeopardised as clause 4.4.1 provided the host government/country with a direct leverage over the laboratory operation. The laboratory independence needs to be assured by not linking the ongoing accreditation to Government/country financial contribution to WADA.

AFLD

Michel Audran, antidoping laboratory director (France)
NADO - NADO

SUBMITTED

Comment 4.4.1: this paragraph shall be removed. The accreditation of the laboratory shall not depend of a financial contribution form the Host country to WADA. It is not only unfair for the laboratory, which activity has nothing to do with this financial contribution but also would give to the government a way to pressure the lab and jeopardize its independancy.

DoCoLab - UGent

Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

SUBMITTED

This clause jeopardizes laboratory independence, allows for laboratories to be pressurized by their governments. We have seen that governments do put pressure on some labs and that this leads to world-wide scandals. Does WADA really want to run the risk for a second Russian scandal?

Additionally, it is hugely disrespectful of WADA to use independent laboratories as a "black mail tool" to force countries to pay their dues.

The clause is simply unacceptable.

Additionally and specifically for my own laboratory: There are 4 NADO's in Belgium. Sometimes there is political turmoil between the different governments of the communities. My lab in particular could be used as a target by 3 NADO's to 'hurt' the community of which I am part. Indeed, if one community does not

pay, my countries dues would not be paid and we as a lab would be punished, while these NADO's might not even be my client.

Drug Control Centre, King's College London

David Cowan, Director (UK)

Other - WADA-accredited Laboratories

SUBMITTED

The proposed linkage of a host country's annual financial contribution to WADA is in direct conflict with the independence and impartiality of the Laboratory. The purpose of the ISL is and should be the quality management of the Laboratory.

"4.4.1 Payment of Host Country's Annual Financial Contribution to WADA For a Laboratory to maintain its WADA accreditation status, its host country shall pay its annual financial contribution to WADA in a timely manner, as determined by WADA."

This paragraph should be removed.

LBCD - LADETEC/IQ - UFRJ

Henrique Marcelo Gualberto Pereira, Prof. (Brazil)

Other - WADA-accredited Laboratories

SUBMITTED

In my perspective the suspension or revocation of a laboratory should be a last step of the process. Suspension should be taken only if a clear risk of havoc the antidoping system is identified.

Pending of the circumstances, the suspension of a laboratory could result in a total collapse of the one. The chance of the laboratory close forever is very real.

Developing a Risk Treatment Plan will allow all stakeholders to have transparent, without the risk of institutional loss.

SADoCoL

Crystal-Anne Barkhuizen, Quality Manager (South Africa)

Other - WADA-accredited Laboratories

SUBMITTED

4.4.1 Payment of Host Country's Annual Financial Contribution to WADA

For a Laboratory to maintain its WADA accreditation status, its host country shall pay its annual financial contribution to WADA in a timely manner, as determined by WADA.

Comment: This clause shall be removed, because it does not form part of the requirements on quality management of a laboratory. The main purpose of the ISL is to ensure that Laboratories comply with quality requirements, report valid and traceable test results, and to achieve, as much as possible, harmonization in Analytical Testing across all Laboratories.

- Firstly: Laboratory independence is jeopardised as clause 4.4.1 provided the host government/country with a direct leverage over the laboratory operation. The laboratory independence needs to be assured by not linking the ongoing accreditation to Government/country financial contribution to WADA.

- Secondly: As described in the draft ISL, version 10, the Code is a Level 1 document and is signed by country signatories (signifying high level representation), while the ISL is a Level 2 document and fittingly represent a lower level of authority when compared to governmental authority. The signing of the Code and its requirements should therefore be linked to its corresponding level of responsibility and authority. It further substantiates the fact that laboratories cannot take responsibility for compliance of a country and for payment of its financial contributions.

Fundació IMIM

SUBMITTED

Rosa Ventura, Laboratory Director (Spain)
Other - WADA-accredited Laboratories

This clause shall be removed as it forms no part of the quality management of a laboratory. The main purpose of ISL is to ensure that Laboratories report valid test results and evidentiary data and to achieve, as much as possible, harmonization in Analytical Testing from all Laboratories.

Laboratory independence is jeopardised as clause 4.4.1 provided the host government/country with a direct leverage over the laboratory operation. The laboratory independence needs to be assured by not linking the ongoing accreditation to Government/country financial contribution to WADA.

LSI Medience Corporation

SUBMITTED

Masato Okano, Director/Dr. (Japan)
Other - WADA-accredited Laboratories

I hope that my host country will contribute to the WADA. However, the ISL should be document for the laboratory performance regarding the analysis.

The lab pay the accreditaion fee anually.

Therefore, this statement should be removed from the WADA ISL.

Seibersdorf Laboratories

SUBMITTED

Guenter Gmeiner, Lab Director (Austria)
Other - WADA-accredited Laboratories

This clause causes a unpredictable harm and a high risk for laboratory operation and cannot be influenced by the laboratory even if best performing.

This clause does not allow future planning of laboratory operations due to dependence external (political) factors. Dependence from the contribution of the host country has no connection to the purpose of the ISL "to ensure that Laboratories and WADA-Approved Laboratories for the ABP report valid test results and based on reliable evidentiary data".

In addition the clause contradicts to clause 4.4.4: The Laboratory shall strictly maintain its full administrative and operational independence. This clause shall be removed completely.

Norwegian Doping Control Laboratory

SUBMITTED

Yvette Dehnes, Laboratory Director (Norway)
Other - WADA-accredited Laboratories

"For a Laboratory to maintain its WADA accreditation status, its host country shall pay its annual financial contribution to WADA in a timely manner, as determined by WADA."

Comment: This clause shall be removed as it forms no part of the quality management of a laboratory. The main purpose of IS for Laboratories is to ensure that Laboratories report valid test results and evidentiary data and to achieve, as much as possible, harmonization in Analytical Testing from all

Laboratories.

Laboratory independence is jeopardised as clause 4.4.1 provides the host government/country with a direct leverage over the laboratory operation. The laboratory independence needs to be assured by not linking the ongoing accreditation to Government/country financial contribution to WADA!

NMI - ASDTL

SUBMITTED

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

Clause 4.4.1 jeopardises laboratory independence. It provides the host government/country with a direct leverage over the laboratory operation.
It has no bearing in relation to the aims of the ISL; reporting of valid test results and evidentiary data or to achieve harmonization in Analytical Testing.
The laboratory independence needs to be ensured by not linking the ongoing accreditation to Government. It is not justifiable that the ISL is used by WADA to collect errant financial contributions.
The laboratories should not be used as a human shield for WADA's governance issues.

Institute for Dopinganalysis and Sportsbiochemistry

SUBMITTED

Kai Weigel, QMB (Germany)
Other - WADA-accredited Laboratories

Contradiction to 4.1.7 Laboratory Independence and Impartiality.

King's College London

SUBMITTED

Alan Brailsford, Anti-doping Scientist (UK)
Other - WADA-accredited Laboratories

It is our view that linking the host countries Annual Financial Contribution to WADA to the laboratories accreditation. This could compromise the laboratories independence and this clause should be removed.

UCLA Olympic Analytical Laboratory

SUBMITTED

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

Suggest removal of 4.4.1 altogether since this clause risks linking a laboratory to its NADO since in most if not all cases the NADO will receive funding from the laboratory's host country. If WADA requires influence to receive necessary financial contributions it is suggested that code-compliance of the NADO rely upon the host country paying its contribution.

Polish Anti-Doping Laboratory

SUBMITTED

Dorota Kwiatkowska, Director of Laboratory (Poland)
Other - WADA-accredited Laboratories

This clause shall be removed as it forms no part of the quality management of a laboratory.

4.4.2 Maintaining ISO/IEC 17025 Accreditation

4.4.2.1 Flexible Scope of Accreditation (1)

UCLA Olympic Analytical Laboratory

SUBMITTED

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

This section requires clarification in order to not open WADA up to increased liability due to the new role this creates as a seeming partner in managing individual laboratory ISO/IEC 17025 scopes of accreditation. The following text should be added to the end of bullet points beginning "New Analytical Testing..." and "WADA-specific Analytical...":

WADA will publish by name the of the analytical testing procedure(s) which it has identified in order that Accreditation Body(s) are aware.

4.4.6 Documenting Implemented Research and Development Activities (1)

UCLA Olympic Analytical Laboratory

Tim Sobolevsky, Senior Scientist (USA)
Other - WADA-accredited Laboratories

SUBMITTED

Article 4.4.6 shall set the research and development budget at 7% not of the total annual operational budget, but rather of its fraction which originates from Code-compliant Anti-Doping Organizations. It needs to be recognized that certain laboratories may have part of their budget coming from sources other than Code-compliant Anti-Doping Organizations.

4.4.10 Publication of Fee Schedule (2)

Seibersdorf Laboratories

Guenter Gmeiner, Lab Director (Austria)
Other - WADA-accredited Laboratories

SUBMITTED

Although it is traceable that testing authorities get a better overview of the scope of testing of the laboratory and therefore the reporting of the testing menus into ADAMS is one possibility, the addition of the price shall not be mandatory but optional for the lab. Esp when it comes to test distribution planning the TAs contact the laboratories on an annual basis to agree upon a price for the whole sample package. And the price per analysis performed is dependent on the total amount of samples received by the TA anyway. Consequently the publication of the price list shall be optional, whereas the analytical menu mandatory.

Swiss Laboratory for Doping Analyses

Tiia Kuuranne, Director (Switzerland)
Other - WADA-accredited Laboratories

SUBMITTED

4.4.10 Publication of Fee Schedule

"... Laboratories shall report into ADAMS an up-to-date price list for each type of analytical method or service that is public to the Anti-Doping Organizations."

Publication of fees on ADAMS is a risk for the point §5.4.7 (contract management). Cherry-picking with prices without detailed discussions related to the services and support does not encourage to negotiate for close partnership and thus, is not helping in increasing the collaboration.

4.4.11 Participating in WADA / Accreditation Body Reassessments and Continuous Assessments during the Accreditation Cycle

4.4.11.2 WADA Assessment (1)

NMI - ASDTL

SUBMITTED

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

add a note as in par. 4.5.1

WADA should inform the TA and RMA for further analysis. In some countries they maybe legal implications due to local penal laws.

4.5 Removal of Samples**4.5.1 Removal of Samples for Further Analysis (1)****UCLA Olympic Analytical Laboratory**

SUBMITTED

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

In second paragraph first sentence, replace the word "transfer" with "removal"

4.5.2 Removal of Samples for Laboratory Quality Assessment (4)**NMI - ASDTL**

SUBMITTED

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

add a note as in par. 4.5.1.

Seibersdorf Laboratories

SUBMITTED

Guenter Gmeiner, Lab Director (Austria)
Other - WADA-accredited Laboratories

Whereas the idea of quality assessment of the laboratory be re-analysis of already analyzed samples by a second lab is shared to improve the laboratory performance, this shall only done for educational purposes. This practice exists in other fields of analytical chemistry and may be a useful tool for continuous improvement in the spirit of ISO 17025.

Penalization or even suspension of a lab based on re-analysis data from a second lab shall not be done. In addition the consent of the TA as the owner of the samples has to be achieved before samples are shifted to another location.

UCLA Olympic Analytical Laboratory

SUBMITTED

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

Since what is being described is not actually an exchange of sample the following edit is suggested:

WADA may also direct the re-analysis of *Samples*, which have met the conditions described in ISL Art. 5.3.3.1, for purposes of Laboratory quality assessment, including the implementation of a system of **exchange transfer** of *Samples* reported as Negative Findings between Laboratories **12**. In this regard, WADA may direct re-analysis of more *Samples* from one Laboratory and less from another Laboratory, according to the criteria established in ISL Art. 6.2.1.1.

In footnote 11 replace "rights" with "right"

In footnote 12 replace "exchange" with "transfer"

Swiss Laboratory for Doping Analyses

Tiia Kuuranne, Director (Switzerland)
Other - WADA-accredited Laboratories

SUBMITTED

4.5.2 Removal of *Samples* for Laboratory Quality Assessment

"WADA may also direct the re-analysis of *Samples*, which have met the conditions described in ISL Art. 5.3.3.1, for purposes of Laboratory quality assessment, including the implementation of a system of exchange of *Samples* reported as Negative Findings between Laboratories **12**. In this regard, WADA may direct re-analysis of more *Samples* from one Laboratory and less from another Laboratory, according to the criteria established in ISL Art. 6.2.1.1."

Both points, 5.3.3.1 and 6.2.1.1 refer to quality assurance, improvement, development and educational nature of the exercise, not to assessment. Consequently, the text should be made clear that the removal of samples is not aimed at sanctioning the laboratory, but to continuous improvement. Furthermore, the objective of the exercise should be made clear for all participating entities in order to guarantee a fair process.

4.6 WADA Monitoring of Accreditation Status (1)

UCLA Olympic Analytical Laboratory

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

SUBMITTED

WADA shall ~~continuously~~ regularly review the compliance of all Laboratories with the requirements listed in the ISL and related Technical Documents and Technical Letters. In addition, WADA shall also conduct an annual review of EQAS results and of relevant routine Analytical Testing issues reported to WADA by stakeholders to assess the overall performance of each Laboratory and to decide its accreditation status.

4.6.4 Loss of WADA Accreditation (2)

Seibersdorf Laboratories

Guenter Gmeiner, Lab Director (Austria)
Other - WADA-accredited Laboratories

SUBMITTED

The list of possible noncompliances with the ISL as basis for the loss of accreditation are much too general. A noncompliance is on the first hand a basis for a corrective action and for continuous improvement. To allow for a traceable basis for the panels involved in the decision of lab suspension or revocation, concrete scenarios of serious noncompliances as basis for a possible loss of accreditation shall be defined. The approach of WAADS is therefore supported, which defines concrete scenarios and evaluates the risks for laboratory operation as well as the antidoping community.

This clause shall be substituted by the risk treatment plan as provided by the WAADS president

Drug Control Centre, King's College London

David Cowan, Director (UK)
Other - WADA-accredited Laboratories

SUBMITTED

A more detailed documented process is needed describing how a Laboratory has its Accreditation Suspended or an Analytical Testing Restriction imposed. The ensuing publicity seriously undermines a Laboratory's credibility and the public probably do not readily distinguish a serious failure (such as falsifying results) from one that is less so. This process is very different from the treatment of an Athlete

or of a National Anti-Doping Organisation and appears unjustified and disproportionate. As written, the process appears to be far too subjective giving the sole discretion to the Chairman of the WADA Executive Committee to take action against a Laboratory. A documented process involving a risk-based approach is needed. Consideration as to whether the erroneous result(s) could adversely affect an Athlete is, of course important. However, the accumulation of "penalty points" alone is not sufficient to ensure that the action against the Laboratory is proportionate.

4.6.4.1 Suspension of Accreditation and Analytical Testing Restriction (1)

Laboratorio de Control de Dopaje de Madrid

SUBMITTED

Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

Comment 1: According to this point, a Laboratory may be suspended due to serious and repeated non compliances with results reporting timelines.

We think that the suspension of the accreditation must not be linked to the reporting timelines, and in case that this point remains in the ISL we think that shall be clearly describe (for example, if in the cases that there is an agreement with the TA that allows the laboratory to exceed the 15 days – reporting time it could be possible that there is not a noncompliance).

Comment 1: The Deputy Director is identified as a senior Laboratory management position (major changes in this position must be notified to WADA). However, the profile for this position is not describe in the ISL.

Qualifications could be:

- At least a Bachelor's Degree (or similar) in one of the natural sciences with extensive and appropriate experience and training in chemical and/or biochemical analysis in the anti-doping area, including the ability to develop analytical methodology.
- Appropriate training and experience of eighth (8) years or more, as well as theoretical knowledge and technical competence in the analysis and interpretation of results for chemical or biological materials, including the classes of substances and methods used in doping;
- Knowledge of relevant WADA Technical Documents, Technical Letters, Laboratory Guidelines and other technical standards;
- Experience in the use of relevant analytical techniques such as chromatography, immunoassays, electrophoresis or mass spectrometry;
- Adequate training in the Laboratory's Management System and thorough understanding of its application into Laboratory processes.

4.6.4.2 Revocation of Accreditation (2)

International Testing Agency

SUBMITTED

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

The use of terminology such as "repeated" or "continuous" is ambiguous. It is recommended that Revocation of Accreditation be grounded on clearer / more objective criteria.

UCLA Olympic Analytical Laboratory

SUBMITTED

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

The following bullet point should be removed since it is too vague to be considered a "noncompliance" and places undo burden of responsibility on the ExCo. The bulleted list in any case is already prefaced by "may be based on, **but not limited to**, the following noncompliances(s):

- Any other cause that materially affects the ability of the Laboratory to ensure the full reliability and accuracy of Analytical Testing and the accurate reporting of test results.

4.6.4.3 Provisional Suspension or Provisional Analytical Testing Restriction

4.6.4.3.1 Mandatory Provisional Suspension or Provisional Analytical Testing Restriction (1)

International Testing Agency

SUBMITTED

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

Where a laboratory loses a number of points threatening its accreditation (provisional suspension), it would be advisable to have another laboratory analyzing the same sample/s to further demonstrate it is a deficiency of the laboratory and not an issue related to the sample (such as sample degradation, wrong labeling of the EQAS, etc.)

4.6.4.5 Disciplinary Proceedings – Suspension, Analytical Testing Restriction or Revocation

4.6.4.5.2 WADA Investigation (1)

Swiss Laboratory for Doping Analyses

SUBMITTED

Tiia Kuuranne, Director (Switzerland)
Other - WADA-accredited Laboratories

4.6.4.5.2 WADA Investigation

- "...either on its own initiative or upon request by any other interested party...",

This definition is extremely vague and may (without restrictions or further definitions) allow e.g. media to request the investigations.

4.6.4.6 Public Notice (1)

Seibersdorf Laboratories

SUBMITTED

Guenter Gmeiner, Lab Director (Austria)
Other - WADA-accredited Laboratories

It is up to the lab anyway to inform its clients about a suspension or a revocation of the accreditation. To post any change in the accreditation status on the WADA web page is enough to clarify the current status. A public notice, distributed worldwide, is therefore not necessary. It simply destroys not only the reputation of a laboratory and makes the way back even more complicated, but has detrimental effects on the whole anti-doping community as the public perception is degraded through the public announcements. It is therefore proposed that no public notice in the form of a WADA press release is done, but the lab reminded to notify its clients from the change in accreditation status.

4.7 Accreditation Requirements for Major Events

4.7.1 Major Event Analytical Testing in the Laboratory Facilities

4.7.1.3 Completing a Pre-Event Report on Facilities and Staff

4.7.1.3.3 (1)

International Testing Agency

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

SUBMITTED

In addition to the items listed in 4.7.1.3.3, it is recommended that the following additional element is added: a full description of the roles and responsibilities of each employee, including the expected shifts and working hours. Furthermore, please specify whether staff or temporary staff scientists can act as Independent Witnesses and/or provide a second opinion for specific analyses (e.g. IRMS, ESA, etc.).

4.8 Approval of non-WADA-accredited Laboratories for the ABP

4.8.2 Maintenance of Status as a WADA-approved Laboratory for the ABP (1)

SADoCoL

Crystal-Anne Barkhuizen, Quality Manager (South Africa)
Other - WADA-accredited Laboratories

SUBMITTED

4.8.2 Maintenance of Status as a WADA-approved Laboratory for the ABP

For a laboratory to maintain its WADA approval status for the ABP, the laboratory shall meet the following requirements:

- Payment by the host country of the annual financial contribution to WADA in a timely manner, as determined by WADA;

Comment: Refer to comment provided under section 4.4.1 related to the responsibilities and authorities on laboratory and governmental levels.

5.0 Application of ISO/IEC-17025 to the Analysis of Samples

5.2 Structural and Resource Requirements

5.2.2 Laboratory Personnel (1)

UCLA Olympic Analytical Laboratory

Tim Sobolevsky, Senior Scientist (USA)
Other - WADA-accredited Laboratories

SUBMITTED

Requirements to scientific laboratory personnel have to be more specific in regards to their qualifications and experience. At present, the wording is such that only a lab director and only in the absence of a PhD shall have “the documented ability to develop analytical methodology and oversee research projects”. It is hard to believe that the design and development of analytical methods should be direct responsibility of a lab director.

It seems that Certifying Scientists are not expected to have this ability (which is acceptable, as long as other scientific personnel exist in the laboratory). Therefore, the ISL should also define the roles and qualifications of other scientific personnel (e.g. Research Scientists, Senior Scientists, and/or Scientific Director) responsible for method development and research activities within a laboratory.

The scientific personnel must have at least a Master’s Degree in chemical and/or biochemical analysis, documented experience of five years or more in the anti-doping area, as well as publications in peer-reviewed literature on method development or drug metabolism and pharmacokinetics.

5.2.2.3 (1)

UCLA Olympic Analytical Laboratory

Brian Ahrens, Laboratory Director (USA)

Other - WADA-accredited Laboratories

SUBMITTED

Since this clause applies to all employees and contracted individuals the requirement for a CV, qualification form(s)/certificate(s) should be removed. In addition, it should be recognized that laboratories themselves may not be allowed to keep such personnel records since they are managed by a larger organization to which the laboratory belongs.

5.2.2.3 The Laboratory shall have records for every *Person* employed by, or under contract with, the Laboratory including a ~~curriculum vitae~~ or qualification form(s)/certificate(s), a job description, records of completed and ongoing training and records of authorization to perform their defined duties.

5.2.2.4 Laboratory Director (1)

UCLA Olympic Analytical Laboratory

Brian Ahrens, Laboratory Director (USA)

Other - WADA-accredited Laboratories

SUBMITTED

The Laboratory Director qualifications and/or characteristics shall include:

and

- Proficiency in English to an extent that allows ~~him/her to adequately~~ performance of his/her functions as part of the international anti-doping community and in accordance with the *Code*, the ISL, Technical Documents, Technical Letters and Laboratory Guidelines.

5.2.3 Laboratory facility and Environmental Conditions

5.2.3.1 Environmental Control (1)

UCLA Olympic Analytical Laboratory

Brian Ahrens, Laboratory Director (USA)

Other - WADA-accredited Laboratories

SUBMITTED

- The Laboratory shall ensure that adequate electrical service is available for scientific instrumentation by provision of an alternative power supply (e.g. UPS system and/or power generators).

5.3 Process Requirements

5.3.1 Reception, Registration and Handling of Samples (3)

International Testing Agency

International Testing Agency, Legal Affairs Manager (Switzerland)

Other - Other (ex. Media, University, etc.)

SUBMITTED

In relation to Art. 5.3.1.5, it is recommended that WADA set up a working group to define acceptability criteria for samples at the time of sample reception in the laboratories. All samples which do not fulfill such criteria should be first registered in ADAMS and should be stored for three months; on the other hand, they should not be analysed.

In relation to Art. 5.3.1.5.2, if the sample does not fulfill the acceptability criteria at the time of the sample reception in the laboratory, it should not be analysed. More importantly, it is strongly recommended that this provision be changed to provide for the scenario whereby a sample is stored but not analysed. The underlying principle would be that all samples shall be registered in ADAMS, but not necessarily analysed - rather they could be placed in long term storage. This is especially important in case dried blood spot sampling is implemented and/or where different developments in anti-doping support such a strategy.

NMI - ASDTL

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

SUBMITTED

5.3.1.6 sample splitting procedure If splitting procedure is carried out in presence of the athlete, there is no more anonymization, it should be carry out in presence of a independent witness.

Institute for Dopinganalysis and Sportsbiochemistry

Kai Weigel, QMB (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

"..

5.3.1.6 Sample Splitting Procedure

..The process of opening and splitting the *Sample* and resealing of the remaining second fraction shall be conducted in accordance with ISL Arts. 5.3.4.5.4.8.7 and 5.3.4.5.4.8.10 "

The presence of the athlete (according to Arts. 5.3.4.5.4.8.7) is in contradiction to the list of irregularities where the information of the athlete shall not be visible. The impartiality of the laboratory can be challenged when the athlete is known before the analytical testing starts.

5.3.2 Storage of Samples (1)

Institute for Dopinganalysis and Sportsbiochemistry

Kai Weigel, QMB (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

"..

5.3.2.1.6 Urine *Sample(s)* with an *Adverse Analytical Finding* or *Atypical Finding*

The Laboratory shall retain the "A" and "B" urine *Sample(s)* with an *Adverse Analytical Finding* or *Atypical Finding* for a minimum of six (6) months after reporting the final analytical result (for the "A" or the "B" *Sample*, as applicable) in ADAMS 22, or for a longer period as determined by the relevant Testing Authority, Results Management Authority or WADA 21.

The Laboratory shall retain the "A" and "B" urine *Sample(s)* with an *Atypical Finding* for a minimum of three (3) months after reporting the "A" *Sample* test result in ADAMS, or for a longer period as determined by the relevant Testing Authority, Results Management Authority or WADA 21. .."

Discrepancy in the storage period of Atypical Findings

Same case in 5.3.2.2.1.3 Plasma/serum

5.3.2.1 Storage of Urine Samples (3)

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

There is an inconsistency in article 5.3.2.1.6 as to retaining ATF-related urines (either > three or > six months).

International Testing Agency

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

SUBMITTED

In relation to Art. 5.3.2.1.2, it is recommended that a defined timeline for freezing the A sample after the aliquots are taken, is clarified in the provision. Indeed, during Major Events, the freezing and thawing cycles take time and are generally not good for sample stability. Please clarify whether the A-samples should be frozen if the confirmation takes place more than 48 hours after reception. In relation to Art. 5.3.2.1.6, it is recommended that the 6-months minimum term be increased to 9 or 12 months, to be on the side of caution.

NMI - ASDTL

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

SUBMITTED

5.3.2.1.6 footnote 22B analysis shall be performed within 3 months

Sample might show degradation signs. Specifically, for whole blood (BT): it is a too long period

The current situation is much better in terms of the sample stability. The rules already in place, also consider potential delays if justified. This should be kept as it is now. See also section 5.3.4.5.4.8.5.

5.3.2.2 Storage of Blood Samples (1)

NMI - ASDTL

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

SUBMITTED

5.3.2.2.1.3

AAF/ATF storage 6 month in first paragraph ATF storage 3 month second paragraph

5.3.2.2.2

Whole blood storage period for AAF is missing

5.3.3 Use, Transfer or Disposal of Samples (1)

International Testing Agency

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

SUBMITTED

In relation to Art. 5.3.3.1, the second bullet point and the last paragraph are not clear insofar as all samples are anonymized for the laboratory and shall not have any means of identification.

5.3.4 Sample Analysis (1)

International Testing Agency

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

SUBMITTED

In relation to the last sentence of Art. 5.3.4.1.2, it is unrealistic to expect that the Laboratory shall use new material to take aliquots for confirmation procedures. It is recommended that such reference be removed.

5.3.4.1 Aliquoting for Analysis (2)

Laboratorio de Control de Dopaje de Madrid

Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

SUBMITTED

Point 5.3.4.1.3. In our opinion the paragraph “The Laboratory shall measure the pH and SG during ITP and CP (“A” and “B” samples) is not clear enough. It seems that the pH and SG shall be measured every time that a CP is carried out, even if the sample is the “A” sample.

UCLA Olympic Analytical Laboratory

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

SUBMITTED

Since it is assumed that the requirement to decant prior to preparing aliquot(s) for the ITPs is to maintain sample integrity, it should also be required that any remaining volume in the decanted portion is discarded following preparation of aliquot(s). Without this additional provision any risk involved with for example pipette tips entering the falcon tube and causing contamination will remain and the clause 5.3.4.1.2 will therefore serve no purpose.

For urine *Samples*, the Laboratory shall obtain, following proper homogenization of the *Sample*, an initial Aliquot containing enough *Sample* volume for all analytical procedures (all Initial Testing Procedures or all intended Confirmation Procedures, as applicable), by decanting the Aliquot from the urine *Sample* container into a secondary container (e.g. a Falcon tube). Procedure-specific Aliquot(s) shall then be taken from the secondary container. **Upon completion of preparation of aliquot(s) the remaining sample in the Falcon tube shall be discarded.**

5.3.4.2 Selection of Analytical Testing Procedures (1)

UCLA Olympic Analytical Laboratory

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

SUBMITTED

Footnote 26 should be removed from the ISL. This information should instead continue to be provided as part of the collection of Technical Documents in force.

5.3.4.4 Validation of Analytical Testing Procedures (3)

NMI - ASDTL

SUBMITTED

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

The detailed description validation shall be moved to a separate document in order to allow easier modification when required.

Norwegian Doping Control Laboratory

SUBMITTED

Yvette Dehnes, Laboratory Director (Norway)
Other - WADA-accredited Laboratories

Footnote 27, on page 74 under

[27] [...] The Validation Report shall indicate whether the Analytical Testing Procedure is Fit-for-

Purpose and shall be approved by the Laboratory Director and the Laboratory Quality Manager.
(Footnote page 74)

Comment: The QM should not approve Validation Reports, because:

1. The ISL wants the QM to be as independent as possible from routine analytical activities (5.2.2.5). This implies that the requirement in footnote 27 makes no logical sense.

2. The QM is heavily involved in the internal audits of the laboratory. To audit the methods oneself has approved, is not good Quality Management.

We have certified scientists that are given validation responsibility by our National Accreditation Agency, after thorough on-site auditing of the scientist in question. They should be able to sign the validation reports they are responsible for.

Recommendation: "...shall be approved by the Laboratory Director or Laboratory Personnel with this responsibility delegated by the Laboratory Director."

Laboratorio de Control de Dopaje de Madrid

SUBMITTED

Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

Point 5.3.4.4 Validation of Analytical Testing Procedures. Note 27.

According to this point the validation report shall be approved by the Lab Director and the Laboratory Quality Manager.

We think that in our laboratory we do not have a problem with the validation reports and the fit-for-purpose of the analytical testing procedures and since a long time ago, in our laboratory the validation report has been approved by the person in charge of the technical quality, that is a person different

from the Laboratory Quality Manager. Therefore, we do not understand the point why we need to generate a conflict between the division of responsibilities among the staff. Moreover, the ISO 17025/2017 leaves the laboratories free to be the ones that determine the distribution of responsibilities, therefore the Laboratory Quality Manager can have profile of much technical knowledge or much quality management knowledge. Additionally, in the point 5.2.2.5 of the ISL the profile defined for the Laboratory Quality Manager is mainly a profile related with Quality

5.3.4.5 Application of Analytical Testing Procedures (1)

Department of Health - National Integrity of Sport Unit

Luke Janeczko, Policy Officer (Australia)

Public Authorities - Government

SUBMITTED

Comment for 5.3.4.5.4.8.12 (which does not appear in WADA Connect) - For clarification, suggest explicit inclusion of substances with reporting limits (are explicitly addressed in 5.3.4.5.4.7.5)

5.3.4.5.3 Application of Initial Testing Procedures (1)

Laboratorio de Control de Dopaje de Madrid

Gloria Muñoz, Lab Manager (Spain)

Other - WADA-accredited Laboratories

SUBMITTED

Point 5.3.4.5.3.8.

In our opinion, the controls also could be near the DL, so we think that the “at or below” can be change by a “near” or “around”.

5.3.4.5.4 Application of Confirmation Procedures (1)

NMI - ASDTL

Catrin Goebel, Director - ASDTL (Australia)

Other - WADA-accredited Laboratories

SUBMITTED

5.3.4.5.4.8.13 CP for endogenous substances

The last paragraph refers to exogenous substances > move at 5.3.4.5.4.8.12

5.3.4.5.4.7 “A” Sample Confirmation Procedure (3)

NADA

Regine Reiser, Result Management (Deutschland)

NADO - NADO

SUBMITTED

Third bullet point: *‘When there is a Presumptive Adverse Analytical Finding for Amphetamine, Methylphenidate, Beta-2 Agonists or Glucocorticoids, the Laboratory may contact the Testing Authority to enquire whether an approved Therapeutic Use Exemption (TUE) exists for the Prohibited Substance(s) detected.’*

The list of substances should be extended to beta-blockers and diuretics, because for these substances many athletes, especially para-athletes and senior athletes, suffering e.g. from high blood pressure, have a TUE. According to our experience for these substances, currently many unnecessary confirmation analyses are conducted.

Sport Ireland

Siobhan Leonard, Director of Anti-Doping & Ethics (Ireland)
NADO - NADO

SUBMITTED

The list of substances should be extended to beta-blockers and diuretics, because for these substances many athletes, especially para-athletes and senior athletes, suffering e.g. from high blood pressure, have a TUE.

Institute of Biochemistry, German Sport University Cologne

Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

5.3.4.5.4.7.3 “A” Sample Confirmation, third bullet point: list of substances should be extended to beta-blockers and diuretics

Third bullet point: *When there is a Presumptive Adverse Analytical Finding for Amphetamine, Methylphenidate, Beta-2 Agonists or Glucocorticoids, the Laboratory may contact the Testing Authority to enquire whether an approved Therapeutic Use Exemption (TUE) exists for the Prohibited Substance(s) detected.*

The list of substances should be extended to beta-blockers and diuretics, because for these substances many athletes, especially para-athletes and senior athletes, suffering e.g. from high blood pressure, have a TUE. According to our experience for these substances, currently many unnecessary confirmation analyses are conducted.

5.3.4.5.6 Alternative Biological Matrices (1)**UCLA Olympic Analytical Laboratory**

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

SUBMITTED

5.3.4.5.6 Alternative Biological Matrices

Any negative Analytical Testing results obtained from hair, nails, oral fluid or other biological material shall not be used to counter *Adverse Analytical Findings* or *Atypical Findings* from urine or blood (including whole blood, plasma or serum) **unless WADA has expressly approved the use of such testing.**

5.3.5 Results Management**5.3.5.1 Review of Results (4)****NADA**

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

The mandatory double check of all ITP results is an enormous increase of workload and increases the prize of the analyses. This most probably leads to a reduction of the total number of analyses.
The double check of ITPs should be performed from two independent analysts.

Institute of Biochemistry, German Sport University Cologne
Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

5.3.5.1.1 The double check of ITPs should (not shall) be performed from two independent analysts

The mandatory double check of all ITP results is an enormous increase of workload and increases the prize of the analyses. This most probably leads to a reduction of the total number of analyses.

NMI - ASDTL

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

SUBMITTED

5.3.5.1.1 A minimum of two (2) qualified Laboratory analysts shall should conduct an independent review of all Initial Testing Procedure raw data and results. The review process shall be recorded.

Modern computer program applications are removing the need for human review processes which should be considered in ISL requirements. The application of Artificial Intelligence fundamentally is a suitable replacement for human review processes as AI does not suffer from fatigue.

Laboratorio de Control de Dopaje de Madrid

Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

SUBMITTED

Point 5.3.5.1.1

We think that the second independent review of all the ITP results could be performed through the review of the processed data (after the integration of chromatographic data, for example or after the treatment of the image with Gas EPO). Every analyst or senior analyst who carried out the second revision will can decide if something about the first data processing shall be changed.

5.3.5.2 Documentation and Reporting

5.3.5.2.6 Test Report

5.3.5.2.6.2 (1)

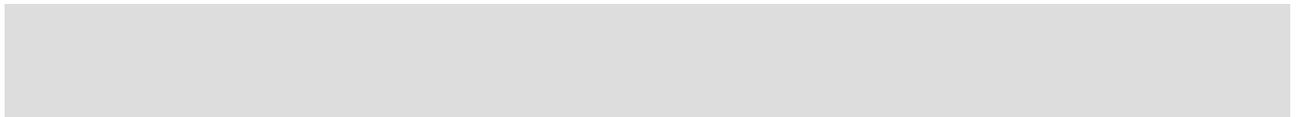
NMI - ASDTL

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

SUBMITTED

The reference to paragraph 5.3.5.2.6.12 should be 5.3.5.2.6.11

5.3.5.2.6.7 (1)



International Testing Agency

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

SUBMITTED

The second opinion should be documented and reported in ADAMS and not only by e-mail and/or in writing. Consider embedding the principle that the data should be evaluated totally, anonymously and independently - avoiding unnecessary exchanges between the two laboratories.

5.4 Management Requirements

5.4.2 Assuring the Quality of Analytical Results

5.4.2.3 Internal Quality Assurance Scheme (iQAS) (1)

Institute for Dopinganalysis and Sportsbiochemistry

Kai Weigel, QMB (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

A double-blind (iQAS) sample necessarily include the reporting of the result in ADAMS. (delete the “double-blind” possibility)

5.4.8 Subcontracting of Analysis (1)

Institute for Dopinganalysis and Sportsbiochemistry

Kai Weigel, QMB (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

"..

5.4.8.2 A Laboratory may subcontract an analysis to another Laboratory, in consultation with the Testing Authority ...

In all such cases, assurance of the maintenance of the appropriate chain of custody throughout the entire Analytical Testing **process is the responsibility of the Director of the Laboratory subcontracting the analysis**, who shall properly instruct the operating laboratory. Such arrangements shall be clearly recorded as part of the *Sample's* documentation and included in the Laboratory Documentation Package, if applicable.

.."

The director of the Lab cannot be held responsible for the work of another laboratory even more the Lab for subcontracted analysis must have a WADA accreditation and therefore it's excepted to obey the chain of custody.

The “assurance” need to be clarified.

6.0 WADA External Quality Assessment Scheme (EQAS) (2)

Department of Health - National Integrity of Sport Unit

Luke Janeczko, Policy Officer (Australia)
Public Authorities - Government

SUBMITTED

A risk assessment based approach is already applied to a number of aspects of WADA management process, such as Guidelines for Implementing an Effective Testing Program and WADA Technical Document for Sport Specific Analysis. WADA should consider whether the External Quality Assessment Scheme and Routine Analytical Testing would be enhanced by evaluating performance in the context of risk rather than the points scoring system that currently exists.

WADA acts to address an issue irrespective of points accumulated by the laboratory. As the current point system is based on the accumulation of points for non-performance over 12 months, there is no dispensation for situations where risk has already been corrected and unlikely to occur again. A laboratory can be suspended even if a risk has been fixed. A laboratory should not be penalised for an issue which has been accepted as being corrected by the WADA Laboratory Expert Group up to 12 months after the fact.

Points-based systems that largely been discontinued in favour of appropriate risk identification and treatment planning. In particular, the International Organization for Standardization in their review of ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories now specifically requires actions to address risks.

The points system has been revised from ISL version 9.0 to 10.0 in order to try and accommodate some of the situations where the process has not worked suitably over the last three years. Simply increasing points or adding more way to accumulate points however does not address the fundamental issue which is that if there is a risk to the anti-testing program WADA should act to ensure the best capabilities and quality outcome for all stakeholders.

The suspension or revocation of a laboratory should be a last resort and only enacted if there is a clear risk which has a very high rating via an assessment of the identified factors. Developing a Risk Treatment Plan will allow all stakeholders to have transparent and documented system.

International Testing Agency

International Testing Agency, Legal Affairs Manager (Switzerland)
Other - Other (ex. Media, University, etc.)

SUBMITTED

Internal quality control material should be prepared by a unique accredited laboratory and provided to all WADA accredited laboratories. The results of the quality control material should be uploaded into ADAMS to follow up on a real time basis the performances of each laboratory and each method. This is especially important for the steroid profile. It is strongly recommended that WADA set-up a XbarM strategy using the sample data at disposal in ADAMS to better understand the possible bias between batches.

6.1 Type of EQAS

6.1.2 Double-Blind EQAS (1)

Swiss Laboratory for Doping Analyses

Tiia Kuuranne, Director (Switzerland)
Other - WADA-accredited Laboratories

SUBMITTED

Please, define the "round" of double-blind EQAS samples for those cases where more than one sample is circulated to the laboratories and evaluated as a bundle.

6.2 EQAS Sample Number and Composition

6.2.1 Number of EQAS Samples (1)

UCLA Olympic Analytical Laboratory

Brian Ahrens, Laboratory Director (USA)
Other - WADA-accredited Laboratories

SUBMITTED

The following bullet point should be added such that WADA's points-based system is evenly applied:

- Additional EQAS samples(i.e. which are not assigned to all laboratories)and any results and/or corrective actions pertaining to their analysis shall not be considered in WADA's points-based EQAS evaluation.

7.0 Evaluation of Laboratory EQAS and Routine Analytical Testing Performance (10)

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

In the introduction of chapter 7.0 it should be mentioned that the provider of the EQAS samples must be certified provider and that for each EQAS sample a documentation must be available.

The provider of the EQAS samples should undergo a certification, which e.g. guarantees that documentations of the test samples are available.

AFLD

Michel Audran, antidoping laboratory director (France)
NADO - NADO

SUBMITTED

Comment 7.0: The penalty points system should be removed as it is more used as a way to punish labs than a way to make them progress. Despite some changes, the cumulation of points for various reason over 12 months can lead to a suspension even if analytical problems have been corrected. Following the new ISO/IEC 17025, risk assesment evaluation could be a good alternative and could be used to evaluate the gravity of the situation for a laboratory and if suspension (partial or total) is necessary.

In the name of all anti-doping laboratories Catrin Goebel, as President of WAADS, will make a detailed proposal of a possible risk assesment that could be adopted in place of the actual point system and will be more appropriate for the labortory. We fully support this proposal.

DoCoLab - UGent

Peter Van Eenoo, Prof.Dr. / director (Belgium)
Other - WADA-accredited Laboratories

SUBMITTED

It has been shown that laboratories have been suspended, while there was no more risk for the anti-doping system (although they had made a mistake), while some others were difficult to suspend as they did not 'break' any real rule. Therefore, I highly encourage revision of this part with an emphasis on risk analysis (in agreement with the new ISO17025) and education/prevention. The Science department has taken a good decision to audit labs on a regular basis (as part of a prevention campaign). This will lead to more "issues" showing up and this should be refelected in the evaluation scheme.

Institute of Biochemistry, German Sport University Cologne

Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

7.0 The provider of the EQAS samples should undergo a certification, which e.g. guarantees that documentations of the test samples are available.

In the introduction of chapter 7.0 it should be mentioned that the provider of the EQAS samples must be certified provider and that for each EQAS sample a documentation must be available

7.0 Evaluation of Laboratory EQAS and Routine Analytical Testing Performance

The Risk Assessment process and methodology is already applied in a number of other WADA management processes, such as the Guidelines for Implementing an Effective Testing Program and WADA Technical Document for Sport Specific Analysis.

Comment: The Risk Assessment process and methodology is already applied in a number of other WADA management process, such as Guidelines for Implementing an Effective Testing Program and WADA Technical Document for Sport Specific Analysis. The evaluation of External Quality Assessment Scheme and Routine Analytical Testing must be evaluated in the context of risk to the athlete and the anti-doping testing program and appropriate risk treatment plans.

- The allocation of penalty points is questioned: If it is allocated and determined by the Lab EG, it is highly debatable, because the Lab EG members are not independent from the laboratories.
- The penalty point system is currently allocated in order to achieve a specific treatment of the a identified risk but because these points are accumulated over 12 months it means a laboratory can be suspended even if a risk has been corrected and could thus no longer occur.
- Penalty on an unsatisfactory CAR should be very carefully evaluated, due to interpretation by different entities on a matter. From a laboratory's point of view, a matter could have been addressed or investigated sufficiently, while it might be deemed insufficiently by an external person.
- If there is a problem, it is agreed that it must be addressed and fixed. However, immediate suspension should be the last resort. Furthermore, a laboratory should not be re-penalised for an issue which has been accepted for correction by the WADA LabEG up to 12 months after it happened.
- On the other hand in cases where there are identified problems, WADA must be able to act irrespective of points accumulated by the laboratory.
- The points system was used historically but has largely now been discontinued in favour of appropriate risk identification and treatment planning. In particular, the International Organization for Standardization in their review of ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories now specifically requires actions to address risks.
- The points system has been revised from the version 9.0 to 10.0 of the ISL to try and accommodate for situations encountered and which did not work sufficiently over the last three years, e.g. WADA was not able to act in order to ensure the quality of the system. But simply increasing points or adding more to accumulate points does not necessarily address the fundamental issue/s. If there is a risk to the anti-testing program, WADA should act appropriately and fittingly to ensure the best capabilities and quality outcome for all stakeholders.
- The suspension or revocation of a laboratory should be a last resort and only enacted if there is a clear risk which has a very high rating via an assessment of the identified factors. Developing a Risk Treatment Plan will allow all stakeholders to have transparency and document system. The below is presented as an example to how this could work.

Risk Category: Capability and Capacity

Risk Description: Specialised analysis technique unavailable because of equipment failure (eg ESA, hGH biomarkers, IRMS)

Risk Consequence: Negative impact on customer satisfaction

Analysis Likelihood: Possible

Analysis Consequence: Minimal

Analysis Risk Rating: Low

Risk treatment Treatment action/s: Laboratory notified clients and WADA that samples will be sent to other WADA lab until corrective action complete

Risk treatment Implementation: Time frame will be depended on specialised analysis technique and presented in plan to WADA LabEG for acceptance.

Risk treatment Monitor & Review: Laboratory to provide progress reports in line with accepted plan.

Risk Category: Service Delivery

Risk Description: Loss in technical capability caused by a critical staff member leaving the organisation, either voluntarily or through retirement.

Risk Consequence: Negative impact on customer satisfaction. Inability to support all required testing services

Analysis Likelihood: Possible

Analysis Consequence: Moderate

Analysis Risk Rating: Medium

Risk treatment Treatment action/s: Laboratory notified WADA with treatment plan and time frame. Plan and time frame accepted by WADA LabEG.

Risk treatment Implementation: 3 to 6 months with appropriate plan present to WADA

Risk treatment Monitor & Review: Immediate notification by email. Follow up with progress report via email. Interview at WADA LEG meeting.

Risk Category: Compliance

Risk Description: Technical breach of an ISL, TD, TN, TL or guideline.

Risk Consequence: Athlete results impacted

Analysis Likelihood: Possible

Analysis Consequence: Moderate

Analysis Risk Rating: Medium

Risk treatment Treatment action/s: Impact review of compliance breach.

Risk treatment Implementation: Preliminary Suspension to Suspension in consideration of impact review.

Risk treatment Monitor & Review: Immediate notification by email.

Risk Category: Reputation

Risk Description: False Adverse Analytical Finding

Risk Consequence: Reputation of athlete. Criticism in international media. Impact on public confidence.

Analysis Likelihood: Rare

Analysis Consequence: Severe

Analysis Risk Rating: Very High

Risk treatment Treatment action/s: Laboratory identified false AAF and reports to WADA. Suspend testing activities pending review of CAR by WADA LEG.

Risk treatment Implementation: 10 days for CAR. 1 day for WADA review of CAR. Suspension or Revocation is warranted or if Satisfactory CAR has addressed problem. Possibility of a hearing by laboratory representative in person (phone, skype,...) before suspension or revocation is actioned.

Risk treatment Monitor & Review: In case of accepted CAR WADA to priorities site visit in annual WADA plan as part of monitoring of CAR. In case of suspension the period should be between 3 and 12 month depending on expected timeline for CA to be implemented. If the laboratory completes required CA before end of suspension period WADA LEG must consider submission and reinstatement if appropriate.

Risk Category: Fraud and Corruption

Risk Description: Breach that could be expected to cause serious damage to the organisations or individuals include manipulation of testing results.

Risk Consequence: Reputation of anti-doping stakeholders

Analysis Likelihood: Rare

Analysis Consequence: Severe

Analysis Risk Rating: Very High

Risk treatment Treatment action/s: Immediate Suspension to Revocation

Risk treatment Implementation: Minimum 1 year, but maximum 2 years to perform and implement corrective action/s.

Risk treatment Monitor & Review: Mandatory site visit by WADA Investigations as well as follow up by Science site visit.

Fundació IMIM

Rosa Ventura, Laboratory Director (Spain)
Other - WADA-accredited Laboratories

SUBMITTED

The evaluation of laboratory performance in EQAS and routine analytical testing should be based on Risk Assessment Process instead in Penalty points system.

The Risk Assessment process and methodology is already applied in a number of other WADA management process, such as Guidelines for Implementing an Effective Testing Program and WADA Technical Document for Sport Specific Analysis.

The evaluation of External Quality Assessment Scheme and Routine Analytical Testing must be evaluated in the context of risk to the athlete and the anti-doping testing program and appropriate risk treatment plans.

The penalty point systems are currently allocated in order to achieve a specific treatment of the a identified risk but because these points are accumulated over 12 months it means a laboratory can be suspended even if a risk has been has been correct and would no longer occur.

If there is a problem it must be addressed and fixed but you must not re-penalise a laboratory for an issue which has been accepted as being corrected by the WADA LabEG up to 12 months after the fact.

On the other hand in cases where there are identified problems WADA must be able to act irrespective of points accumulated by the laboratory.

The points system was used historically but has largely now been discontinued in favour of appropriate risk identification and treatment planning. In particular, the International Organization for Standardization in their review of ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories now specifically requires actions to address risks.

The points system has been revised from ISL version 9.0 to 10.0 in order to try and accommodate some of the situation where the process has not worked suitably over the last three year, that is, WADA was not able to act in order to ensure the quality of the system. But simply increasing points or adding more way to accumulate points does not address the fundamental issue which is that if there is a risk to the anti-testing program WADA should and shall act to ensure the best capabilities and quality outcome for all stakeholders.

The suspension or revocation of a laboratory should be a last resort and only enacted if there is a clear risk which has a very high rating via an assessment of the identified factors. Developing a Risk Treatment Plan will allow all stakeholders to have transparent and document system.

NMI - ASDTL

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

SUBMITTED

The evaluation of External Quality Assessment Scheme and Routine Analytical Testing must be reviewed in the context of risk to the anti-doping testing program and appropriate risk treatment plan developed with appropriate actions, this is inline with the new ISO/IEC 17025:2017.

The Risk Assessment process and methodology is already applied in a number of other WADA management process, such as Guidelines for Implementing an Effective Testing Program and WADA Technical Document for Sport Specific Analysis.

The laboratories shall not be compared to cheating athletes, excluding cases of corruption, thus the performance evaluation of a laboratory should first be a basis for improvement and not a sanction. Only when a laboratory has demonstrated that it is not capable of fulfilling the standards or corrective actions are not satisfactory should a suspension or revocation be considered.

As it stands now the laboratories have many scenarios with no realistic chance of improvement without a sanction by the WADA. This is in clear contrast to the basic standard for analytical testing, ISO/IEC 17025:2017.

The laboratories aim to provide the anti-doping testing services as set out by the standards but continues improvement is always required and through the WADA's support rather than sanctioning better outcomes will be achieved. A sanction, that is, suspension or revocation, should be a last resort because there is a fundamental issue which can not be address through a corrective action in a timely manner. The time frame of the suspension should be related to the time required

If a laboratory has had a problem and the completed corrective action has been reviewed and accepted by the Laboratory Expert Group, the laboratory can not face a sanction 12 months after the fact through accumulation of points when the issue/s has been corrected.

The points system has been revised from ISL version 9.0 to 10.0 in order to try and accommodate some of the situation where the process has not worked suitably over the last three year, that is, the WADA was not able to

act in order to ensure the quality of the system. But simply increasing points or adding more way to accumulate points does not address the fundamental issue which is that if there is a risk to the anti-doping testing program the WADA should and shall act to ensure the best capabilities and quality outcome for all stakeholders.

Developing a Risk Treatment Plan will allow all stakeholders to have transparent and document system which accounts for both laboratories and the WADA. The below is presented several examples for different issues and how risk treatment plan could work.

EXAMPLES:

Risk Category: Capability and Capacity

Risk Description: Specialised analysis technique unavailable because of equipment failure (eg ESA, hGH biomarkers, IRMS)

Risk Consequence: Negative impact on customer satisfaction

Analysis Likelihood: Possible

Analysis Consequence: Minimal

Analysis Risk Rating: Low

Risk treatment Treatment action/s: Laboratory notified clients and WADA that samples will be sent to other WADA lab until corrective action complete

Risk treatment Implementation: Time frame will be depended on specialised analysis technique and presented in plan to WADA LabEG for acceptance.

Risk treatment Monitor & Review: Laboratory to provide progress reports in line with accepted plan.

Risk Category: Service Delivery

Risk Description: Loss in technical capability caused by a critical staff member leaving the organisation, either voluntarily or through retirement.

Risk Consequence: Negative impact on customer satisfaction. Inability to support all required testing services

Analysis Likelihood: Possible

Analysis Consequence: Moderate

Analysis Risk Rating: Medium

Risk treatment Treatment action/s: Laboratory notified WADA with treatment plan and time frame. Plan and time frame accepted by WADA LabEG.

Risk treatment Implementation: Time frame determined by laboratory as part of treatment plan; 3 to 6 months with appropriate plan present to WADA

Risk treatment Monitor & Review: Immediate notification by email. Follow up with progress report via email. Interview at WADA LEG meeting.

Risk Category: Compliance

Risk Description: Technical breach of an ISL, TD, TN or TL. Consideration of the impact of the breach.

Risk Consequence: Athlete results impacted

Analysis Likelihood: Possible

Analysis Consequence: Moderate

Analysis Risk Rating: Medium

Risk treatment Treatment action/s: Impact review of compliance breach.

Risk treatment Implementation: Present impact review to WADA. Preliminary Suspension to Suspension in consideration timeline required to conduct corrective action.

Risk treatment Monitor & Review: Immediate notification by email.

Risk Category: Reputation

Risk Description: False Adverse Analytical Finding

Risk Consequence: Reputation of athlete. Criticism in international media. Impact on public confidence.

Analysis Likelihood: Rare

Analysis Consequence: Severe

Analysis Risk Rating: Very High

Risk treatment Treatment action/s: Laboratory identified false AAF and reports to WADA. Suspend testing activities for the analytical process concerned pending review of CAR by WADA LEG

Risk treatment Implementation: -10 days for CAR. 5 days for WADA review of CAR. Suspension (partial or total) or Revocation is warranted or if Satisfactory CAR has addressed problem. Possibility of a hearing by laboratory representative in person (phone, skype,...) before suspension or revocation is actioned.

Risk treatment Monitor & Review: In case of accepted CAR WADA to priorities site visit in annual WADA plan as part of monitoring of CAR. In case of suspension the period should be between 3 and 12 month depending on expected timeline for CA to be implemented. If the laboratory completes required CA before end of suspension period WADA LEG must consider submission and reinstatement if appropriate.

Risk Category: Reputation

Risk Description: False negative result (doping control or EQAS sample)

Risk Consequence: Athlete results impacted (not sanctioned). Negative impact on customer satisfaction

Analysis Likelihood: Rare

Analysis Consequence: Moderate

Analysis Risk Rating: Medium

Risk treatment Treatment action/s: Reports to WADA and notification to TA/RMA

Risk treatment Implementation: -10 days for CAR. 5 days for WADA review of CAR.

Risk treatment Monitor & Review: Immediate notification by email. Follow up during assessment cycle by the

national accreditation body.

Risk Category: Fraud and Corruption

Risk Description: Breach that could be expected to cause serious damage to the organisations or individuals include manipulation of testing results.

Risk Consequence: Reputation of anti-doping stakeholders

Analysis Likelihood: Rare

Analysis Consequence: Severe

Analysis Risk Rating: Very High

Risk treatment Treatment action/s: Immediate Suspension to Revocation and independent evaluation of the situation by WADA Investigations and LabEG.

Risk treatment Implementation: Suspension or revocation period dependant on time period required for implementation of corrective action/s.

Risk treatment Monitor & Review: Mandatory site visit by WADA Investigations as well as follow up by Science site visit.

Norwegian Doping Control Laboratory

Yvette Dehnes, Laboratory Director (Norway)

Other - WADA-accredited Laboratories

SUBMITTED

The evaluation of External Quality Assessment Scheme and Routine Analytical Testing must be reviewed in the context of risk to the anti-doping testing program and appropriate risk treatment plan developed with appropriate actions, this is inline with the new ISO/IEC 17025:2017.

The laboratories shall not be compared to cheating athletes, excluding cases of corruption, thus the performance evaluation of a laboratory should first be a basis for improvement and not a sanction. Only when a laboratory has demonstrated that it is not capable of fulfilling the standards or corrective actions are not satisfactory should a suspension or revocation be considered.

As it stands now the laboratories have many scenarios with no realistic chance of improvement without a sanction by the WADA. This is in clear contrast to the basic standard for analytical testing, ISO/IEC 17025:2017.

The Risk Assessment process and methodology is already applied in a number of other WADA management process, such as Guidelines for Implementing an Effective Testing Program and WADA Technical Document for Sport Specific Analysis.

The laboratories aim to provide the anti-doping testing services as set out by the standards but continues improvement is always required and through the WADA's support rather than sanctioning better outcomes will be achieved. A sanction, that is, suspension or revocation, should be a last resort because there is a fundamental issue which can not be address through a corrective action in a timely manner. The time frame of the suspension should be related to the time required.

If a laboratory has had a problem and the completed corrective action has been reviewed and accepted by the Laboratory Expert Group, the laboratory can not face a sanction 12 months after the fact through accumulation of points when the issue/s has been corrected.

The points system has been revised from ISL version 9.0 to 10.0 in order to try and accommodate some of the situation where the process has not worked suitably over the last three year, that is, the WADA was not able to act in order to ensure the quality of the system. But simply increasing points or adding more way to accumulate points does not address the fundamental issue which is that if there is a risk to the anti-doping testing program the WADA should and shall act to ensure the best capabilities and quality outcome for all stakeholders.

Developing a Risk Treatment Plan will allow all stakeholders to have transparent and document system which accounts for both laboratories and the WADA. The below is presented several examples for different issues and how risk treatment plan could work.

See examples of Risk Treatment Plan posted by Catrin Goebel on behalf of WAADS.

Laboratorio de Control de Dopaje de Madrid

Gloria Muñoz, Lab Manager (Spain)
Other - WADA-accredited Laboratories

SUBMITTED

We think that an evaluation based in an analysis of the risk, as is proposed by WAADS, could be a very interesting an valuable way of evaluate the Laboratory EQAS and Routine Analytical Testing Performance. It leaves space for improvement, which is in line with the philosophy of ISO17025 / 2017.

Polish Anti-Doping Laboratory

Dorota Kwiatkowska, Director of Laboratory (Poland)
Other - WADA-accredited Laboratories

SUBMITTED

Revision of Penalty Points system to Risk Treatment Plan.

These points are accumulated over 12 months it means a laboratory can be suspended even if a risk has been has been correct and would no longer occur.

If there is a problem it must be addressed and fixed but you must not re-penalise a laboratory for an issue which has been accepted as being corrected by the WADA LabEG up to 12 months after the fact.

On the other hand in cases where there are identified problems WADA must be able to act irrespective of points accumulated by the laboratory.

The suspension or revocation of a laboratory should be a last resort and only enacted if there is a clear risk which has a very high rating via an assessment of the identified factors.

7.1 Evaluation of EQAS Results (2)

NADA

Regine Reiser, Result Management (Deutschland)
NADO - NADO

SUBMITTED

The term 'WADA-approved method' is not defined. It is not clear when a method is WADA-approved. Is it connected with a certificate?

The term 'WADA-approved method' should be defined.

Institute of Biochemistry, German Sport University Cologne

Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

7.1 The term "WADA-approved method" should be defined

The term "WADA-approved method" is not defined. It is not clear when a method is WADA approved. Is it connected with a certificate?

7.2 Evaluation of Laboratory Performance

7.2.1 False Adverse Analytical Finding

7.2.1.2 False Adverse Analytical Finding during routine Analytical Testing (1)

LBCD - LADETEC/IQ - UFRJ

SUBMITTED

Henrique Marcelo Gualberto Pereira, Prof. (Brazil)

Other - WADA-accredited Laboratories

In my perspective the suspension or revocation of a laboratory should be a last step of the process. Suspension should be taken only if a clear risk of havoc the antidoping system is identified. Pending of the circumstances, the suspension of a laboratory could result in a total colapse of the one. The chance of the laboratory close forever is very real. Developing a Risk Treatment Plan will allow all stakeholders to have transparent, without the risk of institutional loss

7.2.1.3 False Adverse Analytical Finding for blind or double-blind EQAS sample (1)

Institute for Dopinganylsis and Sportsbiochemistry

SUBMITTED

Kai Weigel, QMB (Germany)

Other - WADA-accredited Laboratories

"..

The WADA LabEG shall review the Laboratory's Corrective Action Report within ten (10) working days, or within a timeline otherwise determined by WADA, and **establish the source of the incorrect result** as either a technical/methodological error or a clerical/administrative error:

- Technical or methodological error

If the Root Cause Analysis investigation performed by the Laboratory identifies the error as technical or methodological, the Laboratory will be initially imposed twenty (20) penalty points in accordance with the ISL Points Scale Table."

Unclear wording. Either the CAR of the Lab identifies the source of error or shall the LabEG establish the type of error? What happen if there are different opinions? The type of error rules the penalty points.

7.2.2 False Negative Finding (1)

NADA

SUBMITTED

Regine Reiser, Result Management (Deutschland)

NADO - NADO

There is an essential role of the LabEG (7.2.2 '*...if the Laboratory's Corrective Action Report is considered unsatisfactory by the LabEG...*'). Their decision-making process, in particular between meetings (quick feedback to Laboratory), needs to be described, e.g. minimum number of (concordant?) votes.

7.3 Overall Laboratory Evaluation (4)

To increase or to keep the capacities of the laboratories, a sensible approach would be to disestablish the suspension of labs as sanction and replace it by a sanction system with focus on education and corrective actions. Suspensions lead to an immediate decrease of capacities and also to a long-term effects by brain drain, financial problems, loss of reputation etc.

The suspension of laboratories as sanction should be disestablished and replaced by a sanction system with focus on education and corrective actions.

The current rule of addressing 10 points for a sample, reported falsely negative, in combination of a laboratory provisional suspension after 20 points, i.e. 2 false negatives within a 12 months period, is by no means proportional to the harm upon a laboratory and the complete loss of its reputation after a provisional suspension; not to mention the financial disaster, a laboratory faces after provisional suspension of its accreditation. This holds especially in cases, where the samples reported falsely negative derive from EQAS tests. No concrete harm can be attributed to such a non-compliance. The harm to athletes not being caught is an abstract one and not concrete. Even in laboratories with high reputation and high analytical quality adverse analytical findings can be overlooked, simply because of the human factor, like in every other discipline. And the risk is exponentially increased by the total number of samples analyzed per year.

The number of sanction-points after reporting of a false negative sample should be reduced (at least below 5). In case of a satisfactory corrective action by the laboratory no points shall be attributed.

Every athlete has the right of a direct and fair hearing and be present and heard by the panel. Suspensions of laboratories are issued without the presence of the laboratory director or his/her representative at the time frame of the decision of the panel. Decisions are taken based on the documentation provided. Questions of the panels cannot be directly attributed to the responsible person. The following publication of the suspension on the WADA website destroys the reputation of a laboratory and leads to a loss of its economic basis and is therefore a severe sanction.

Before a provisional suspension and especially before publication of a provisional suspension of a laboratory ('google sanction'), the laboratory should have the right of legal processes (hearing, CAS hearing).

Table on page 116/117: There seem to be a copy/paste error claiming 'Suspension / Analytical Testing Restriction' as sanction following 'Satisfactory CAR'.

To avoid confusion, the timing for Late Submission penalties should be expressed in working days.

The parallel definition of suspension based on

- elements of an offense or (three bullet points on p. 115)
- penalty points (p. 116/117)

is difficult to interpret and partially inconsistent, e.g.

- three False Negative Findings in EQAS will lead to 30 penalty points (Article 7.2.2., p. 116) and
- Penalty Points ? 30 lead to Provisional Suspension (table p. 117) but
- footnote 69 states '*... A Laboratory may have a maximum of ...three independent False Negative Findings per 12-month period*'.

For consistency reasons, the ? sign in table p. 117 should turn into >.

NMI - ASDTL

Catrin Goebel, Director - ASDTL (Australia)
Other - WADA-accredited Laboratories

SUBMITTED

Institute of Biochemistry, German Sport University Cologne

Hans Geyer, Deputy Head (Germany)
Other - WADA-accredited Laboratories

SUBMITTED

7.3. The suspension of laboratories as sanction should be disestablished and replaced by a sanction system with focus on education and corrective actions.

To increase or to keep the capacities of the laboratories, a sensible approach would be to disestablish the suspension of labs as sanction and replace it by a sanction system with focus on education and corrective actions. Suspensions lead to an immediate decrease of capacities and also to a long-term effects by brain drain, financial problems, loss of reputation etc."

7.3. The number of sanction-points after reporting of a false negative sample should be reduced (at least below 5). In case of a satisfactory corrective action by the laboratory no points shall be attributed

The current rule of addressing 10 points for a sample, reported falsely negative, in combination of a laboratory provisional suspension after 20 points, i.e. 2 false negatives within a 12 months period, is by no means proportional to the harm upon a laboratory and the complete loss of its reputation after a provisional suspension; not to mention the financial disaster, a laboratory faces after provisional suspension of its accreditation. This holds especially in cases, where the samples reported falsely negative derive from EQAS tests. No concrete harm can be attributed to such a non compliance. The harm to athletes not being caught is an abstract one and not concrete. Even in laboratories with high reputation and high analytical quality adverse analytical findings can be overlooked, simply because of the human factor, like in every other discipline. And the risk is exponentially increased by the total number of samples analyzed per year

7.3. Before a provisional suspension and especially before publication of a provisional suspension of a laboratory ("google sanction"), the laboratory should have the right of legal processes (hearing, CAS hearing)

Every athlete has the right of a direct and fair hearing and be present and heard by the panel. Suspensions of laboratories are issued without the presence of the laboratory director or his / her representative at the time frame of the decision of the panel. Decisions are taken based on the documentation provided. Questions of the panels cannot be directly attributed to the responsible person. The following publication of the suspension on the WADA website destroys the reputation of a laboratory and leads to a loss of its economic basis and is therefore a severe sanction.

Swiss Laboratory for Doping Analyses

Tiia Kuuranne, Director (Switzerland)
Other - WADA-accredited Laboratories

SUBMITTED

For the overall laboratory evaluation, the definition of the time tags should be defined for double-blind (db) EQAS-samples, i.e. what will be the starting date for any potential time of suspension or other disciplinary actions in case if several dbEQAS samples are considered as one "round".

1.

A new Annex B: Procedural Rules for the Disciplinary Committee of the ISL, has been added, whereas the revised ISL Code of Ethics remains as Annex A.